HQCA
Health Quality Council of Alberta

REVIEW OF QUALITY ASSURANCE IN CONTINUING CARE HEALTH SERVICES IN ALBERTA

April 30, 2014

Promoting and improving patient safety and health service quality across Alberta

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FOREWORD

For a healthcare system to function safely and well, all aspects of that system must be continuously monitored and evaluated so that areas needing improvement are identified and acted upon. At the request of the Minister of Health, the Health Quality Council of Alberta (HQCA) has closely examined the adequacy and monitoring of quality assurance processes and quality management within continuing care. This included the structures and processes that support the quality and safety of publicly funded continuing care (home care, supportive living, and long-term care services).

When these structures and processes are in place and functioning optimally – with a focus on continuous monitoring and improvement – they support good quality of care for clients and residents in our continuing care system.

Thank you to the many stakeholders who participated in interviews or otherwise gave of their time to help ensure we gained the broadest possible understanding of current practices in quality and safety management within continuing care. I also offer thanks to the members of the review team for their hard work and thoroughness over the past number of months.

The HQCA is committed to working closely with the Ministry of Health and Alberta Health Services to support the implementation of recommendations made in this report for the benefit of all Albertans receiving continuing care. As much as this review was about systems and processes, those clients who are served in this health system were always in our sights.

Patricia Pelton, Acting Chief Executive Officer, HQCA
Calgary, Alberta
April 30, 2014

EXECUTIVE SUMMARY

Continuing care is an integrated range of services supporting the health and well-being of individuals living in their own home, a supportive living environment, or a long-term care facility.[1] The individuals can be of any age and have a vast range of healthcare conditions. Many thousands of Albertans receive continuing care services each year in a variety of settings.

In the fall of 2013, pursuant to Section 15 (1) of the *Health Quality Council of Alberta Act*,[2] the Minister of Health directed the Health Quality Council of Alberta (HQCA) to conduct a review that would examine the adequacy and monitoring of quality assurance and quality management processes of home care services delivered directly by Alberta Health Services (AHS) and by providers under contract to AHS. The request for this review was prompted by concerns raised publicly and in the media. Subsequently, following concerns raised about a few events in different long-term care centres in the province, the Minister directed the HQCA to expand its review from just home care to all of continuing care services.

The review was conducted by the HQCA's Quality Assurance Committee (QAC) in accordance with Section 9 of the *Alberta Evidence Act*.[3]

Scope

This review was limited to examining the adequacy and monitoring of quality assurance and quality management processes in publicly funded continuing care health services. Privately funded continuing care services were out of scope, as was any examination of access to continuing care services, the type or scope of service provided, the funding of continuing care service, the individual providers of continuing care service, the Accommodation Standards (or quality assurance activities related to the Accommodation Standards), or aspects of contract management beyond quality management.

Methodology

The QAC gathered information from multiple sources:

- Fifty-six interviews with key stakeholders including the Ministry of Health, AHS, associations related to continuing care services, and service providers.
- A scan of healthcare quality management frameworks nationally and of activities related to quality management within continuing care.
- More than 500 documents, including those supplied by the Ministry of Health, AHS, continuing care associations, and interviewees as well as through Internet searches.
- Published and grey literature in quality management in home care services, focusing on aspects such as frameworks, quality indicators, adverse events, performance reporting systems, quality management best practices, and accreditation.
- Published and grey literature from the past 10 years in quality management and safety management to identify an inventory of models of safety management and quality management in healthcare settings and other industries.

The information was synthesized into components of a quality and safety management framework. System deficiencies and opportunities for improvement in the quality management systems currently in place for continuing care in Alberta were then identified.

The focus of the review was on determining how the Ministry of Health and AHS ensure the quality of continuing care health services delivered directly by AHS and by providers under contract to AHS.

Findings

Contracts need to be standardized and compliance monitoring can be improved

Given that a significant proportion of services in continuing care are provided through a contractual arrangement with external service providers, having a standardized contract is an important oversight tool that supports consistent quality and safety management across continuing care. The contract holds service providers accountable for reporting and performing quality improvement and quality assurance activities. AHS monitors the providers' compliance with obligations outlined in the contract, conducts financial audits, and reviews performance information.

Continuing care contracts are not yet standardized across the province, resulting in variable contract accountabilities. AHS is in the process of moving all new and existing continuing care service providers towards a master services agreement (MSA) that will be consistent across the province; however, moving legacy contracts to the new MSA has been difficult and is taking longer than originally expected.

Currently, responsibility for monitoring continuing care contracts is held in various AHS departments, resulting in an 'everybody is responsible' situation. The risk in this kind of approach is that 'nobody is responsible' as it is believed that responsibility lies elsewhere.

Core functions of quality and safety management can be strengthened

The main client assessment system in use within continuing care settings, developed by interRAI, is being underused for quality monitoring and evaluation at all levels of the continuing care system. The interRAI instruments are in use to varying degrees across the province, which means that the reporting and use of the interRAI data, including quality indicators, is variable. Consistency of indicators, measures, and reporting will be enhanced with the maturing of the interRAI data collection processes and when all historical and current data is included in the Alberta Continuing Care Information System (ACCIS). Variability across AHS zones and service provider organizations in the resources available to support analysis and reporting was also noted.

Continuing care lacks a standardized, consistent, and province-wide approach to administering client and family experience surveys. A variety of survey questionnaires and processes are deployed across the three continuing care service streams and across the many service provider organizations. This prevents any opportunity to compare between sites or across or between AHS zones or to aggregate data at a provincial level for reporting and quality improvement purposes.

No single repository exists to collect continuing care safety information from across the province. At present, various mechanisms allow for the reporting of safety information, and contracted providers and patients/families are not able to use AHS' Reporting and Learning System. This significantly limits the ability to identify and analyze safety issues across the continuing care system, and thus greatly impedes effective quality and safety management because safety information is not widely shared to enable the organization to learn and make improvements.

The duplication of auditing processes in continuing care results in redundancies and inefficiencies at the provider, zone, and provincial levels. Together, the various processes result in the potential for six onsite audits or inspections within the same year. In addition, the content of the different audits and standards

often overlap. There were differing views on how to improve the process and which organization (Ministry of Health or AHS) should be responsible for the audits.

There is considerable variability within and across the three continuing care service streams as to each service provider's accreditation status and the use and requirement of accreditation as a quality management tool by AHS.

Clarification of roles, responsibilities, and accountabilities is needed

Quality and safety management in continuing care lacks clarity in roles, responsibilities, and accountabilities among the Ministry of Health, AHS, and contracted service providers. Within AHS alone there is a lack of clarity regarding roles and responsibilities for quality and safety management. This results in confusion and duplication of effort. Areas of overlap and uncertainty include the auditing of compliance to standards, monitoring of service provider contracts, and management of patient harm events.

Recommendations

Three main areas were identified to improve the management of quality and safety in Alberta's continuing care system. The first area relates to AHS contract management and oversight of contracted providers. The second area involves strengthening core functions of quality and safety management in continuing care. The third addresses clarification of roles, responsibilities, and accountabilities for quality and safety management in continuing care.

Recommendation 1

AHS develop a plan, with timeframes, to move all legacy continuing care contracts over to the standardized master services agreement.

Recommendation 2

AHS make explicit where the responsibility and accountability for continuing care contract compliance monitoring and oversight resides.

Recommendation 3

The Ministry of Health and AHS improve auditing processes in continuing care including CCHSS, Accommodation Standards, and accreditation with a goal to remove redundancy and improve efficiency. When redesigning the audit processes, some general principles should be considered:

- Consistent application across the province and across the three continuing care streams.
- Auditing to be done by a group that is removed from frontline or zone operations.
- Separation of the auditing process from the process that provides quality improvement support and coaching.

Required actions

- The Ministry of Health and AHS explore combining the Accommodation Standards and CCHSS auditing processes.

- The Ministry of Health and AHS publicly report the results of CCHSS audits.
- The Ministry of Health and AHS ensure that the CCHSS audit tool includes mechanisms to assess the rigour of the provider's quality improvement program to verify that performance measures are used to continuously identify improvement opportunities and that processes are in place for implementing improvement strategies.

Recommendation 4

The Ministry of Health and AHS provide clarity on the role and requirement for accreditation in quality and safety management for continuing care.

Required actions

- The Ministry of Health review, and revise if required, the ministerial directive *Mandatory Accreditation in Alberta's Health System*, to provide clarity regarding the requirement for mandatory accreditation for continuing care contracted service providers.
- AHS develop a plan, with clear timelines, to ensure and monitor the accreditation status of all contracted service providers.

Recommendation 5

The Ministry of Health and AHS complete the implementation and support the full use of the interRAI assessment instruments and the Alberta Continuing Care Information System (ACCIS).

Required actions

- Make interRAI information available to all continuing care stakeholders for continuous quality and safety management.
- Ensure appropriate, dedicated resources at all levels (micro and macro) to support measurement, analysis, monitoring, and evaluation of interRAI information and the identification and implementation of improvement opportunities.
- Provide the public with access to site/provider-level quality information.

Recommendation 6

The HQCA continue to build on the work completed to date to establish valid, reliable, and consistent province-wide client and family survey tools and processes for long-term care, supportive living, and home care that support and facilitate quality improvement efforts throughout the continuing care system.

Recommendation 7

AHS develop a plan for incorporating all continuing care safety information (e.g., reportable incidents, hazards/hazardous situations, close calls, patient harm events, concerns, and PPC reports) from AHS staff, physicians, and contracted service providers to effectively identify and analyze safety issues, share safety information across the continuing care system, and inform system improvement.

Recommendation 8

The Ministry of Health and AHS develop an accountability matrix for continuing care that clearly delineates the lines of responsibility and accountability for quality and safety management from the Ministry to AHS, and from AHS to contracted service providers.

Recommendation 9

AHS ensure clear lines of accountability and responsibility for quality and safety management in continuing care.

Supplementary finding

In a Canada-wide scan, including Alberta, nowhere could a comprehensive quality and safety management model or framework for continuing care be found. Many jurisdictions demonstrated aspects of quality and safety management (measure/monitor/evaluate, identify opportunities for improvement, and improve the system); however, they were seldom integrated or captured in a comprehensive framework document. Throughout Alberta's continuing care health system, the elements of quality management are employed, but to varying degrees of implementation, and without adequate overall integration.

Alberta Health Services (AHS) has begun the development of a quality management framework for continuing care with a supporting risk management structure, and a measurement and reporting framework. The Ministry of Health has also contributed to this work through collaboration and development of a: (1) Health Systems Outcome and Measurement Framework; and (2) environmental scans on governance structure for quality assurance and healthcare risk assessment. In addition, the Ministry's 2014-2017 business plan has identified the need to develop a framework that will assure Albertans of the quality and safety of care provided in healthcare facilities.

However, despite the work completed to date, the province is still lacking an overarching integrated approach to quality and safety management. The HQCA has identified a plan to develop a provincial quality and safety management framework in its 2014-2015 business plan. Without a consistent and overarching quality and safety management framework, there is a risk that quality and safety resources are used ineffectively, that care staff are overburdened with inefficient monitoring activities, and that the system cannot as readily learn about and adopt practices that improve the quality and safety of continuing care for Albertans.

A provincial quality and safety management framework that standardizes terminology and the application of core principles and functions would ensure a systemic way of thinking about and approaching quality management that would help to embed these important concepts into Alberta's overall health system now and in the future. This approach should incorporate the dimensions of quality and areas of need of the Alberta Quality Matrix for Health, and should be applicable to various sectors and service-specific areas within Alberta's healthcare system. In fact, as identified above, Alberta would be leading the way in developing and establishing a provincial framework for quality and safety management.

The development of a provincial quality and safety management framework would benefit from the engagement of health system stakeholders from across the province and representing health service sectors, provider and health professional organizations, the Ministry of Health, and academia. In addition, utilizing national and international experts in quality and safety management from healthcare and non-healthcare industries for external validation would ensure all aspects of quality and safety management have been addressed.

PROJECT OVERVIEW

Background

In 2013 significant public and media attention became focused on home care services in Alberta. Concerns centred on the home care request for proposal (RFP) process in Edmonton, and on missed visits to home care clients. On September 9, 2013, pursuant to Section 15 (1) of the *Health Quality Council of Alberta Act*,[2] the Minister of Health directed the Health Quality Council of Alberta (HQCA) to conduct a review that examined the adequacy and monitoring of quality management and quality assurance processes of home care services delivered directly by Alberta Health Services (AHS) and by providers under contract to AHS (Appendix I).

Through the fall, media attention became focused on other services within continuing care, beyond home care, following concerns raised by families about a small number of events that occurred in different long-term care centres in the province. In response, on December 2, 2013, the Minister of Health directed the HQCA to expand the review from just home care to all of continuing care services (Appendix II).

Scope

This report focuses not on specific events, but on system-wide, comprehensive approaches to improving quality and safety for the benefit of all Albertans receiving continuing care services.

The scope of the review was limited to publicly funded continuing care services. Privately funded continuing care services were out of scope. As well, the review was to exclude any examination of access to continuing care services, the type or scope of services provided, the funding of continuing care services, the individual providers of continuing care service, the Accommodation Standards (or quality assurance activities related to the Accommodation Standards), or aspects of contract management beyond quality management (Appendix III).

Methodology

This review was conducted using the *Systematic Systems Analysis: A Practical Approach to Patient Safety Reviews* as a guide.[4] The methodology encourages a systemic view of the healthcare system; that is, "how all parts of the healthcare system play a role", rather than a focus on "only one particular factor in isolation".[4] The following describes the approach taken to collect and analyze information and to develop recommendations and required actions.

Collection of information

- Fifty-six interviews were conducted with key stakeholders including the Ministry of Health, AHS, associations related to continuing care services, and providers (direct delivery, contracted, not-

for-profit, and for-profit). The names of individuals invited to participate and whether or not they participated have been, and will be, kept confidential. No client[1] names or identifiers have been, nor will be, disclosed.

- An Internet scan was undertaken of healthcare quality management frameworks nationally and of activities related to quality management within continuing care.
- More than 500 documents were reviewed, including those supplied by the Ministry of Health, AHS, associations, and interviewees as well as through Internet searches conducted by members of the review team.
- A review of the published and grey literature was conducted on the topic of quality management in home care services. It focused on a number of aspects of quality management including frameworks, quality indicators, adverse events, performance reporting systems, quality management best practices, and accreditation.
- A review of the published and grey literature from the past 10 years was completed on quality management and safety management to identify an inventory of models of safety management and quality management in healthcare settings and other industries (e.g., nuclear power, aviation, and other transportation industries).

Analysis of information

In the analysis phase, the information that was gathered was synthesized into components of a quality and safety management framework. System deficiencies and opportunities for improvement in the quality management systems currently in place for continuing care in Alberta were then identified.

Development of recommendations

Recommendations for system-level improvements were developed to mitigate the quality and patient safety issues with the adequacy and monitoring of quality management in the provision of continuing care. They are presented in this report as 'issues, analysis, and recommendations'.

[1] In this report, 'client' is a term used to describe a patient, client, or resident in all three streams of continuing care.

Review team

The review was conducted under the HQCA's Quality Assurance Committee (QAC) in accordance with Section 9 of the *Alberta Evidence Act*.[3] The *Review of Quality Assurance in Continuing Care Services in Alberta* Quality Assurance Committee included:

- Carmella Duchscherer, RRT BHS(RT) MPA, Quality & Safety Review Team Lead, HQCA
- W. Ward Flemons, MD FRCPC, Quality Assurance/Quality Improvement Consultant
- John P. Hirdes, PhD, Gerontology, Quality and interRAI Consultant
- Donna MacFarlane, RN, Patient Safety Lead, HQCA
- Charlene McBrien-Morrison, RT(CSLT) MBA, Executive Director, HQCA
- Donna Stelmachovich, RN, Continuing Care Consultant

The following people provided input into the report:

- Rinda LaBranche, RN BEd MEd, Patient Safety Lead, HQCA
- Christiane Langtry, Administrative Assistant, HQCA
- Anette Mikkelsen, BSc(Psych) BSc(PT) MBA, Quality and Safety Initiatives Lead, HQCA
- Dianne Schaeffer, Executive Assistant, HQCA
- Eric Wasylenko, MD BSc MHSc, Health Ethics and End of Life Consultant

INTRODUCTION TO CONTINUING CARE

The needs of people receiving continuing care services in community and facility settings are complex and multidimensional in nature. People receiving these services are often affected by several chronic health conditions at once (referred to as multimorbidity), and the interactions among these conditions increase the complexity of their needs and costs of care.[5] In addition, some of the conditions that increase with age (e.g., Alzheimer's disease and related dementias) affect a person's medical condition, ability to function in tasks of daily life, mental functioning, mood, and behaviour. These are further complicated by psychosocial changes (e.g., widowhood) and environmental challenges (e.g., accessibility in the built environment). Therefore, service providers across the continuum of care must employ a variety of medical, rehabilitative, psychosocial, and environmental strategies to support the ability of people to live as independently as possible.

Frailty is an important underlying challenge affecting many people in continuing care. Disease diagnoses on their own provide inadequate information to understand the changes these individuals will experience over time.[6] Frailty is a broader clinical concept that considers a person's diminished ability to cope with challenges as a result of declining physical and cognitive capacity. There are debates about the precise definition and measurement of frailty,[7,8] but there is a broad-based consensus that frailty is a fundamental problem that affects most older people in the latter stages of their lives.

The response to the needs of people in continuing care typically involves multidisciplinary teams of health and social service providers from different sectors in the continuum of care. Their experience is often affected by how different sectors (primary care, hospitals, emergency departments, rehabilitation, home care, long-term care facilities) work together in a co-ordinated, collaborative manner. The care received in one context may affect the transition to another (e.g., the quality of home care can affect rates of long-term care placement) and services are often provided by different organizations simultaneously, making the accountability for the quality of care shared, rather than exclusive.

Continuing care in Alberta

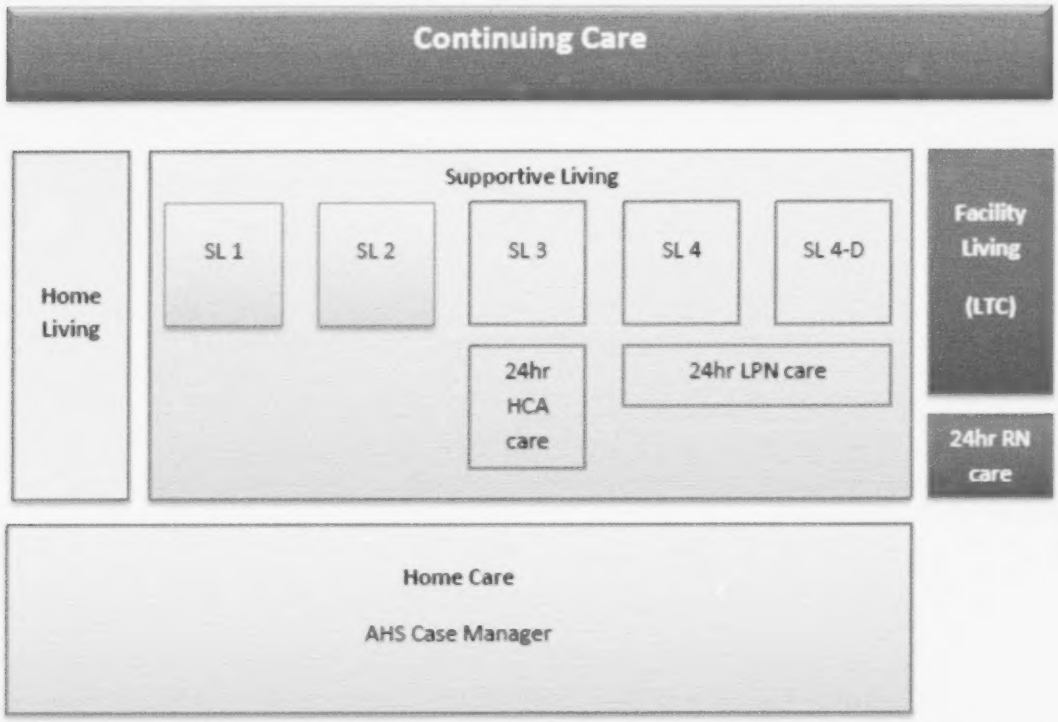
Continuing care in Alberta is an integrated range of services supporting the health and well-being of individuals living in their own home, a supportive living environment, or a long-term care facility.[1] The individuals can be of any age and have a vast range of different healthcare conditions. Care can be provided in three different settings, or 'streams': home living (i.e., home care), supportive living, and facility living (i.e., long-term care). Figure 1 shows the three streams and associated services within continuing care.

Alberta Health Services (AHS) explains: "In addition, Alberta Health Services may be able to offer various models of care within these streams. This may include adult family care, group homes, special centres for Alzheimer's disease and related disorders, transitional living settings and various types of seniors' day programs. Individuals who receive publicly funded health services through Alberta Health Services will undergo a needs assessment to determine their care and service needs."[9]

'Coordinated Access' for continuing care describes a "province-wide, person-centred, integrated service access and delivery approach"; the purpose of Coordinated Access is to provide reasonable, timely, and appropriate access to publicly-funded continuing care based on availability and determination of unmet health needs.[1] The need for services is determined through standardized assessment tools and processes. Coordinated access is supported by case management.

Case management is a collaborative process between the case manager (a healthcare professional), the client, family, and other health professionals who may be involved in the client's care, including the family physician. Clients in either the home living or supportive living streams are assigned an AHS case manager, who is responsible for providing transitional care and assessment to determine if the client's needs should be met with different services or in a different living setting. When a client transitions to a long-term care facility, the facility's registered nurse is responsible for coordinating the client's care.

Figure 1: The continuing care system



HCA – Healthcare aide
LPN – Licensed practical nurse
RN – Registered nurse

Home living (home care)

Home care is a health service that supports individuals' wellness and independence, with the goal to help them remain safe and independent in their own home or care setting for as long as possible. Home care supports Albertans of all ages and provides an array of services including health promotion and teaching, treatments, care at end-of-life, rehabilitation, home support and maintenance, assistance to maintain social connections, and support for family or others who assist clients. Home care includes both professional health services and personal care services, as outlined in Table 1.[10] Professional staff include registered nurses, rehabilitation professionals, and respiratory therapists.

Table 1: Professional health services and personal care services provided by home care

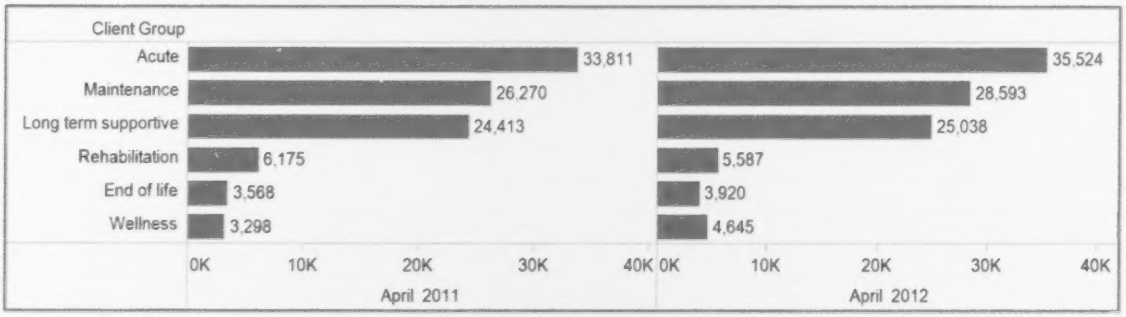
Professional Health Services	Personal Care Services
Prevention, screening, and service intake	Personal hygiene (bathing and grooming)
Assessment of health status and/or medical conditions	Dressing
Performing treatments and procedures	Toileting and incontinence management
Rehabilitation to achieve maximum function	Dining and oral care
Medication administration	Assisting with medications
End-of-life care (palliative)	Mobilization and transferring
Teaching and supervising self-care	
Teaching care and procedures to family or other caregivers	
Teaching and supervising home support service providing individual care and performing assigned activities	

People of all age groups receive home care support, including pediatrics (0-18 years), adults (19-64 years), and seniors (65 years and older). There are six main groups of people who receive home care support:[11]

- **Acute:** for individuals who need immediate or urgent, time-limited interventions (within three months) to improve or stabilize a medical or post-surgical condition.
- **Rehabilitation:** for people with a stable health condition that is expected to improve with a time-limited focus on rehabilitation to improve function. The treatment plan specifies goals and expected duration of therapy.
- **Long-term supportive:** for individuals who are at significant risk for institutionalization due to unstable chronic health conditions, and/or living conditions, and/or personal resources.
- **End-of-life:** for people who, in one's best clinical judgment, have an end-stage disease and are expected to live less than six months. Judgment should be substantiated by well-documented disease diagnosis and deteriorating clinical path.
- **Maintenance:** for individuals with chronic stable health conditions, living conditions, and personal resources who require ongoing support to remain at home.
- **Wellness:** for people who are medically stable with a chronic medical condition or functional limitation. These clients are normally seen infrequently or in a clinic-type setting.

The largest group of clients receiving home care support is 'acute', followed by 'maintenance'. Figure 2 shows the number of home care clients, broken down in to the six categories, for 2011 and 2012.

Figure 2: Home care clients by type

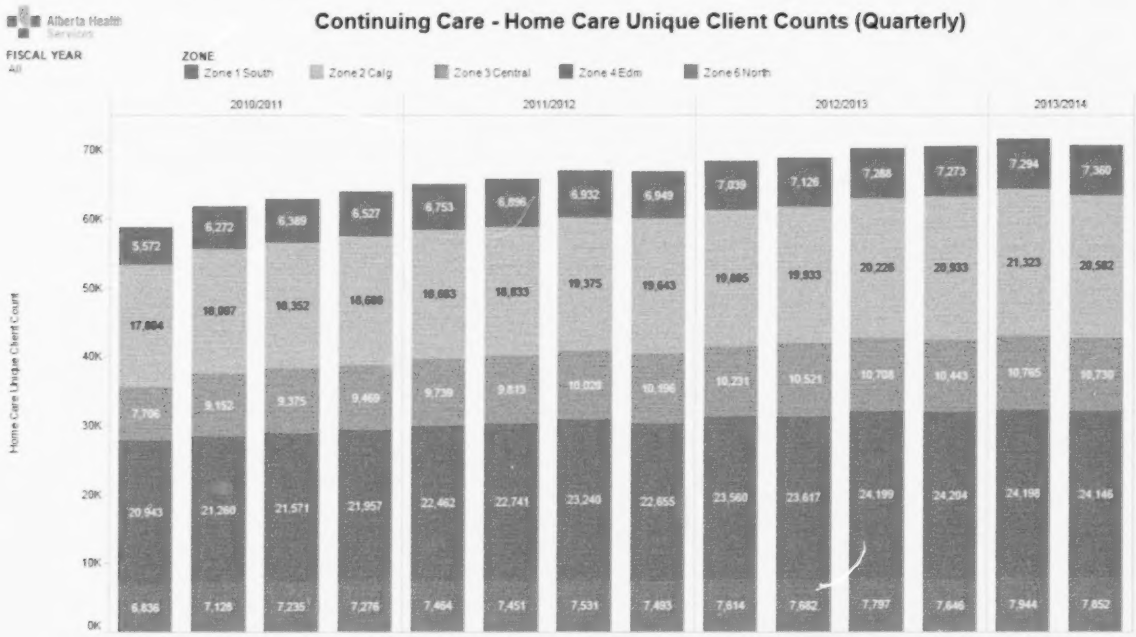


Source: AHS Data Integration, Measurement and Reporting, 2013. Limitations: The counts are of patients who had an assigned client group AND were attending in a home care program at the time of the assignment of a group.

Respite care is another type of service that is available for home care clients. It gives family caregivers a short period of relief from their caregiving responsibilities.

More than 100,000 clients were served by the home care program in 2012/13.[12] The average age of clients in the long-term supportive and maintenance program was 78. The home care program in Alberta is growing at an average rate of five per cent a year and slightly faster in Calgary and Edmonton at seven per cent. In the Calgary and Edmonton zones alone, more than 16,000 home care visits are made each day. (Source: AHS STATIT Reporting System, 2014)

Table 2: Home care unique client counts by quarter, by zone



	2010/2011				2011/2012				2012/2013				2013/2014	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Zone 1 South	5,572	6,272	6,389	6,527	6,753	6,896	6,932	6,949	7,039	7,126	7,288	7,273	7,294	7,360
Zone 2 Calg	17,804	18,097	18,352	18,686	18,683	18,833	19,375	19,643	19,895	19,933	20,226	20,933	21,323	20,582
Zone 3 Central	7,706	9,152	9,375	9,469	9,739	9,813	10,020	10,196	10,231	10,521	10,708	10,443	10,765	10,730
Zone 4 Edm	20,943	21,260	21,571	21,957	22,462	22,741	23,240	22,655	23,560	23,617	24,199	24,204	24,198	24,146
Zone 5 North	6,836	7,128	7,235	7,276	7,464	7,451	7,531	7,493	7,614	7,682	7,797	7,646	7,944	7,852
Grand Total	58,861	61,909	62,922	63,915	65,101	65,734	67,098	66,936	68,339	68,879	70,218	70,499	71,524	70,670

Table 2 shows the *unique* client counts quarterly for each zone. What it does not show is that some clients move in and out of home care; for example, they may start and end care in quarter one, and then receive care again in a later quarter. Therefore, the total number of client counts is actually much higher.

All individuals living in Alberta with a valid healthcare card are eligible to receive home care services. Anyone can refer a person to home care for assessment of need, including the client, family, friends, neighbours, or health professionals. Each AHS zone operates a centralized home care office with a toll-free number, where registered nurses provide intake and screening using standardized tools. Most offices operate at a minimum of 14 hours a day between 8 a.m. and 10 p.m.; in Calgary and Edmonton, however, this service is provided 24 hours a day, seven days a week. Home care can be operated by private for-profit, private not-for-profit, or public operators.

Supportive living

"Supportive living provides accommodation in a home-like setting where people can remain as independent as possible while they have access to accommodation and services that meets their changing needs."[13] Supportive living serves the needs of a wide array of individuals that range from frail seniors to young adults with mental health or physical disabilities. Supportive living settings vary by size, appearance, and types of services provided; the types of settings include seniors' lodges, group

homes, and mental health and designated supportive living accommodations.[13] These supportive living settings can be operated by private for-profit, private not-for-profit, or public operators.[13] The services provided vary, but may include 24-hour monitoring, emergency response, security, meals, housekeeping, and life-enrichment activities.

"Designated supportive living is where AHS controls access to a specific number of spaces according to an agreement between AHS and the operator."[13] There are four levels within supportive living. In the two lowest levels – supportive living level 1 (SL1), which is residential living, and supportive living level 2 (SL2), which is lodge living – support is scheduled and provided by home care. The higher supportive living levels include 24-hour support:

- Supportive living level 3 (SL3) is for people who require a greater level of care than can be provided through scheduled care in an individual's home. SL3 clients are medically stable and may have mild dementia with no risk of wandering, do not pose a risk to themselves or others, may need a one-person transfer and have increased care needs, some of which cannot be scheduled. SL3 facilities are staffed with on-site healthcare aides 24 hours a day to provide personal care and support. A registered nurse from home care continues to provide professional care and assessment, oversight, and direction.[14]
- Supportive living level 4 (SL4) applies to people who have high levels of need for personal care and support as well as the need for professional on-site nursing care. SL4 clients have complex medical needs that are predictable and that cannot be met at home, may have varying levels of dementia, and require assistance with daily activities. SL4 facilities are staffed with on-site healthcare aides 24 hours a day, and nursing care and assessment is provided by an on-site licensed practical nurse (LPN). A registered nurse from home care continues to provide professional care and assessment, coordination of care, oversight, and direction and is available on call 24 hours a day.[15]
- Supportive living level 4 dementia (SL4D) is for people with moderate to severe dementia, who may be at a high risk of wandering and unpredictable behaviours but who are not a safety risk to themselves or others. Dementia cottages are places where care can be provided to clients in later stages of dementia or other forms of cognitive impairment.[15]

Supportive living level 3 and 4 facilities are operated as a partnership between AHS and the facility operator. The operator's services are contracted and funded by AHS, and each AHS zone has first right of access to the funded spaces in SL3 and SL4. Table 3, *below*, shows the number of SL3, SL4, and SL4D spaces in the province.

Table 3: Number of SL3, SL4, and SL4D spaces in Alberta[12]

Number of Beds/Spaces	As of March 31, 2013
SL3	1,552
SL4	4,531
SL4D	1,896
Total SL3, SL3 and SL4D	**7,979**

Based on an individual's assessed unmet need, personal care and health services are publicly funded. The accommodation-related costs, such as rooms, meals, housekeeping, and any other additional services that are provided by the operator, are covered by the client. However, "affordable supportive living spaces that were funded in part with capital grant dollars from the province cannot charge residents more than the equivalent of what the maximum accommodation fees are for a private room in a long-term care facility".[13]

Facility living (long-term care)

Long-term care facilities are sometimes referred to as nursing homes or auxiliary hospitals. They are designed for individuals with complex, unpredictable medical needs who require 24-hour on-site registered nurse assessment and/or treatment.[16] Individuals who require long-term care are those with complex, end-of-life care needs, serious fluctuations in health status, a need for medication management, or who have unpredictable, unstable behaviour that places the individual or others at risk.[16] Nursing care is provided by registered nurses, licensed practical nurses, and 24-hour on-site healthcare aids, who provide most of the care. In Alberta, 70 per cent of the nursing staff in long-term care are healthcare aides, 17 per cent are registered nurses, and 13 per cent are licensed practical nurses.[17]

All long-term care facilities are either operated by AHS or are under contract to AHS.[9] Some facilities are stand-alone buildings, while others may share space in a building with other services or may even be located within an acute care hospital. As of December 31, 2013, there were a total of 14,594 long-term care spaces in Alberta, of which 9,779 were contracted. Table 4 indicates the number of long-term care sites and spaces, per zone.

Table 4: Long-term care capacity by AHS zone, as of December 31, 2013

Zone	LTC sites	LTC spaces
Calgary	39	5,003
Central	42	2,287
Edmonton	41	5,193
North	34	1,265
South	18	846
Total	**174**	**14,594**

Source: AHS Corporate Accountability & Monitoring

Residents in long-term care facilities are responsible for paying for the accommodation-related charges according to standardized rates established by the Ministry of Health. Residents do not pay for medications prescribed by a physician or for transfers to and from a hospital in an ambulance.[9]

Roles and responsibilities in continuing care

Responsibility and accountability within continuing care can best be described by looking at the different roles of the provincial government (including the Ministry of Health), the health authority (Alberta Health Services), and the contracted service providers.

The provincial government

The Government of Alberta establishes the legislative and regulatory framework in which the health system operates. The following legislation has particular importance to the continuing care system:

- *Supportive Living Accommodation Licensing Act* (and the Supportive Living Accommodation Licensing Regulation)
- *Nursing Homes Act*
- *Hospitals Act*
- *Public Health Act* (and the Co-ordinated Home Care Program Regulation)
- *Health Professions Act*
- *Regional Health Authorities Act*
- *Protection for Persons in Care Act*

In addition to these acts, there are also two sets of standards that apply to continuing care:

- The Continuing Care Health Service Standards (CCHSS) apply to all publicly funded continuing care health services regardless of whether they are provided directly by, or under contract to, AHS.[18] These standards are based on six principles: client-centred care, integrated care teams, client and family involvement, wellness and safety, quality assurance, and quality improvement.[18] Operators and programs are inspected and audited to determine compliance with the CCHSS.[18]
- The Accommodation Standards are mandatory across the province for any publicly funded facility providing care for four or more adults. There are two sets of Accommodation Standards, one specific to long-term care and another specific to supportive living. A system of inspection ensures operators are compliant with or exceeding the standards before receiving a licence to operate; continued compliance with the standards is required to maintain a licence.[19]

The Ministry of Health provides funding to AHS for the provision of healthcare services, including continuing care services. The Ministry of Health does not directly provide continuing care services; however, it sets strategic and directional policy, as well as establishes legislation and standards for the health system in Alberta. In addition, the Ministry sets broad system expectations and, through measuring and monitoring of performance and accountability, provides public assurance that the health system is working appropriately.

Alberta Health Services

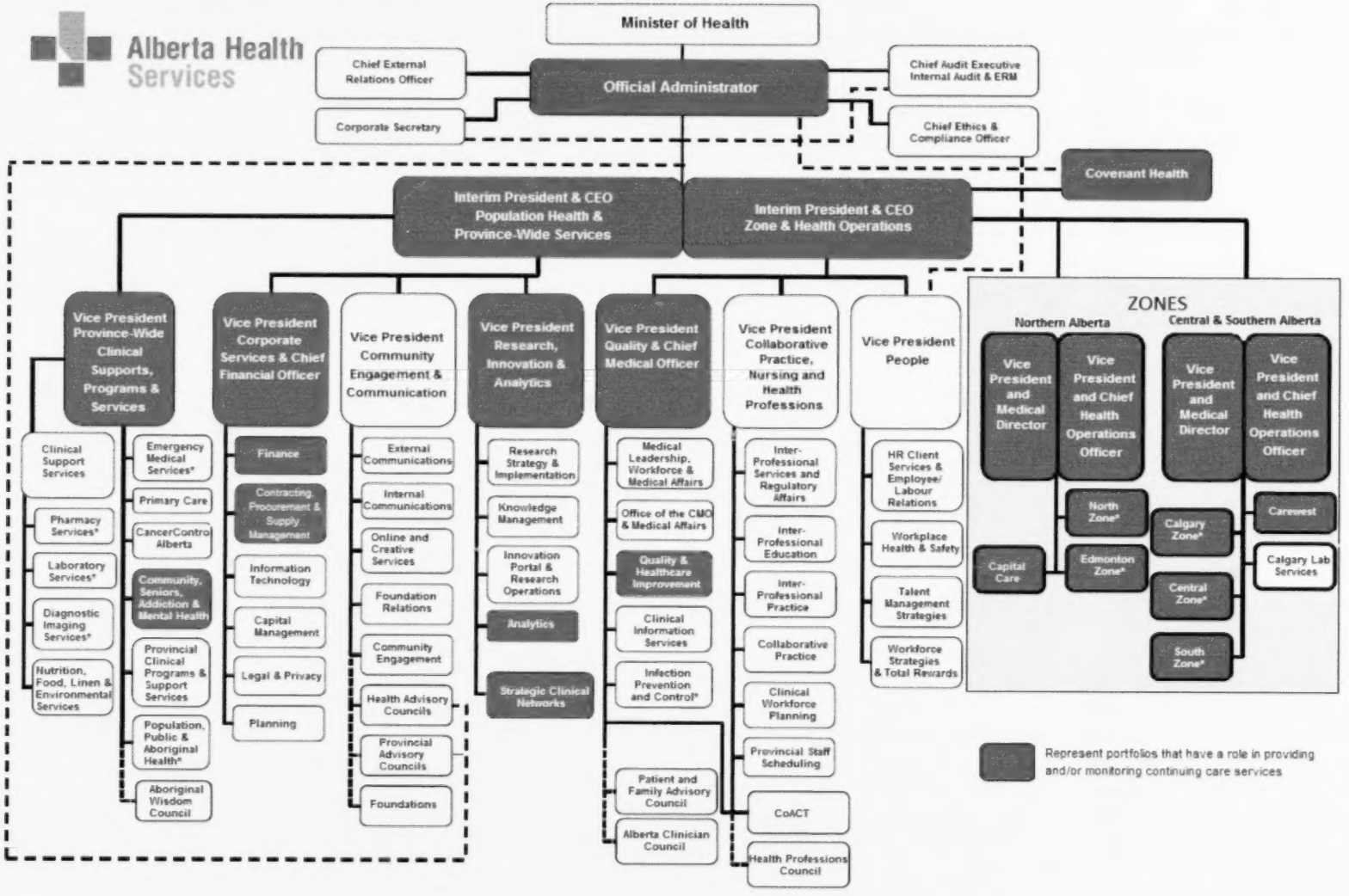
As the health authority, AHS is responsible for delivering healthcare services in Alberta, including continuing care services, with the budget allotted by the Ministry of Health. AHS sets operational policy that aligns with the Ministry's directional policy; implements the CCHSS; and monitors, evaluates, and

reports on the continuing care system's performance. AHS may provide continuing care services directly or may delegate the delivery of services through a contract agreement with a provider.

AHS is structured with a mixed model of provincial and zonal decision-making and accountability. There are a number of departments within AHS that have a role in providing and monitoring the delivery of continuing care services (Figure 3):

- AHS has established a 'zone' structure consisting of the North, Central, South, Calgary, and Edmonton zones. The zones are responsible for the operational delivery of continuing care services within their geographical area.
- Community, Seniors, Addictions and Mental Health is a small provincial team that liaises with government and external partners, develops strategy, leads the development of province-wide policy, and drives provincial consistency.
- Contracting, Procurement and Supply Management (CPSM) supports each of the zones by providing the legal and business expertise to establish contracts.
- Seniors' Health Strategic Clinical Network (SCN) was established to bring together a diverse group of stakeholders to focus on reshaping and improving continuing care and acute care services for the elderly. Over the long term, the Seniors Health SCN will focus on three major platforms: (1) healthy aging and seniors, (2) aging brain care, and (3) anticipating an aging Alberta.[20]
- Quality Healthcare Improvement (QHI) supports all of AHS in quality, accreditation, patient safety, and patient concerns management activities.
- Data Integration, Measurement and Reporting (DIMR) supports the collection, analysis, and reporting of health system data.
- Business Advisory Services provides business and financial expertise to the zone operational leadership and to the Community, Seniors, Addictions and Mental Health Department.

Figure 3: AHS Continuing care functional structure



Source: Retrieved from AHS website and modified by the HQCA.

In addition, there are a number of provincial and zonal committees with membership from among these various departments, which are tasked with specific activities. For example, there is a Home Care Redesign Committee and an Integrated Continuing Care Steering Committee.

Contracted service providers

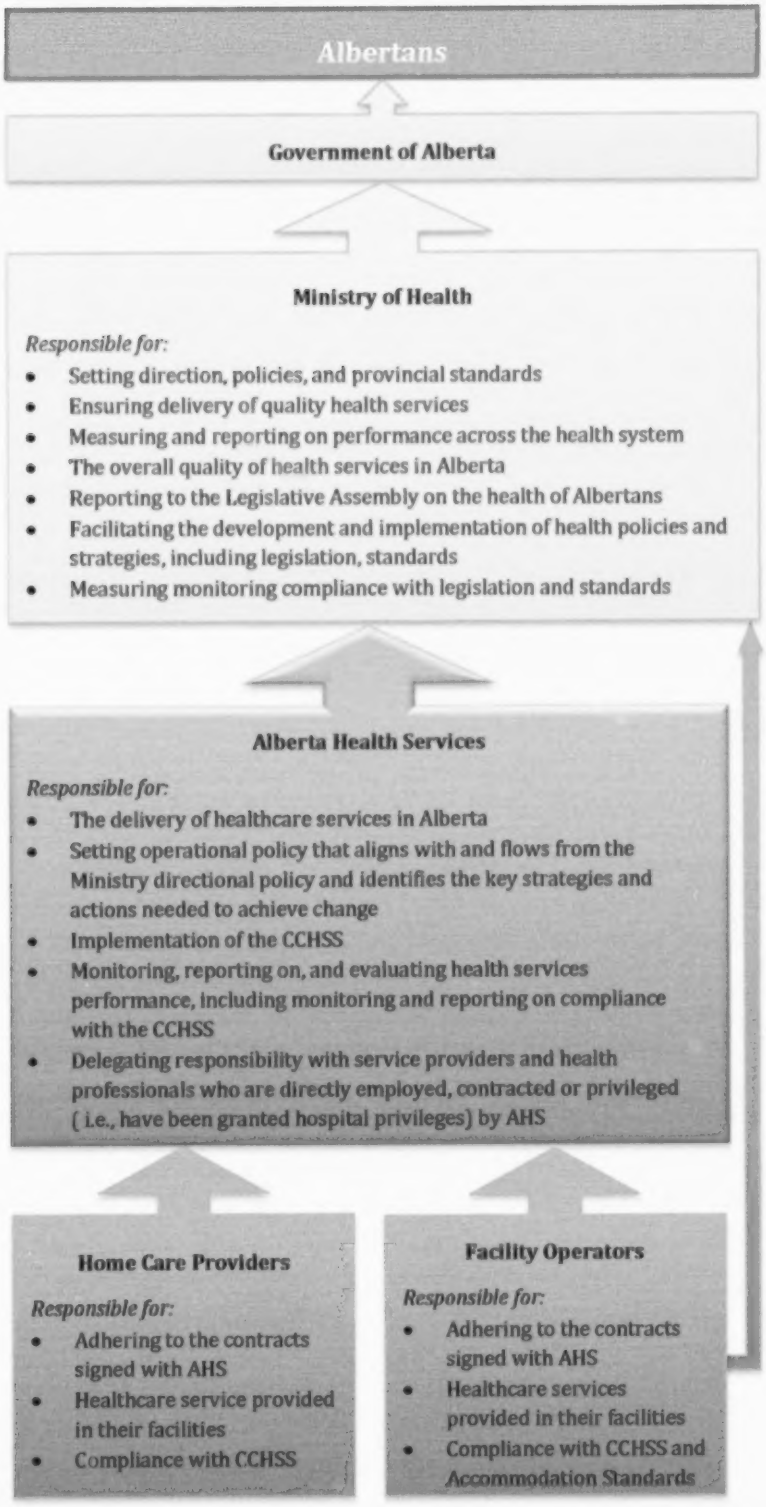
AHS contracts different service providers to provide health services in all three streams of continuing care. These contracted service providers are responsible for:

- Adhering to the signed contract with AHS.
- Providing continuing care services.
- Complying with the CCHSS and, where applicable, the Accommodation Standards.[21]

To enable access to information, especially for contracted providers who cannot access information on AHS's internal website, the Continuing Care Desktop has been available since 2006.[22] The Ministry of Health provided resources, computers, and training to continuing care service providers to implement the desktop. The Continuing Care Desktop provides information about the CCHSS, a library, education, provincial, and zone-specific information, as well as information geared to healthcare aides.[23]

Figure 4 shows the responsibility and accountability structure from providers through to Albertans, with the accountability relationship depicted with arrows.

Figure 4: Continuing care system responsibility and accountability structure


Albertans
Government of Alberta
Ministry of Health
Responsible for:
Setting direction, policies, and provincial standards
Ensuring delivery of quality health services
Measuring and reporting on performance across the health system
The overall quality of health services in Alberta
Reporting to the Legislative Assembly on the health of Albertans
Facilitating the development and implementation of health policies and strategies, including legislation, standards
Measuring monitoring compliance with legislation and standards
Alberta Health Services
Responsible for:
The delivery of healthcare services in Alberta
Setting operational policy that aligns with and flows from the Ministry directional policy and identifies the key strategies and actions needed to achieve change
Implementation of the CCHSS
Monitoring, reporting on, and evaluating health services performance, including monitoring and reporting on compliance with the CCHSS
Delegating responsibility with service providers and health professionals who are directly employed, contracted or privileged (i.e., have been granted hospital privileges) by AHS
Home Care Providers
Responsible for:
Adhering to the contracts signed with AHS
Healthcare service provided in their facilities
Compliance with CCHSS
Facility Operators
Responsible for:
Adhering to the contracts signed with AHS
Healthcare services provided in their facilities
Compliance with CCHSS and Accommodation Standards

Source: Retrieved from the Accountability Framework CCHSS revision 2009/10 and modified by the HQCA

AN OVERVIEW OF QUALITY AND SAFETY MANAGEMENT

"High-performing healthcare systems are those that have created effective frameworks and systems for improving care that are applicable in different settings and sustainable over time."[24]

There are various and often overlapping definitions for activities whose goal is improved outcomes for patients. The following definitions are presented to provide clarity to the discussion:

- **Quality assurance (QA):** those activities that are carried out to set standards and to monitor and improve performance so the care provided will satisfy stated or implied needs.[25] The term QA system refers to "organizations and processes for defining, assuring, maintaining, and improving quality", and "the extent to which they provide assurance that essential standards of quality are being met".[26]
- **Quality improvement (QI):** activities aimed at improving performance; an approach to the continuous study and improvement of the processes of providing services to meet the needs of the individual and others.[25] Through the use of teams, improvement opportunities are identified and employees are empowered to take action on these opportunities using "practical methods and tools" and "incorporating statistical methods and measurement" to identify problems and monitor progress.[27,28,29]
- **Quality management:** an ongoing effort to provide services that meet or exceed client expectations through a structured, systematic process for creating organizational participation in planning and implementing quality improvements.[25] Quality management is broad and incorporates quality assurance and quality improvement activities.
- **Safety management:** a systematic approach to managing safety. This approach should include the necessary organizational structural elements, including those for: governance and management responsibility and accountability; policies and procedures; reporting, investigating, evaluating, recommending and improving.[30]

The concept of quality management originated more than a century ago at the time of an emerging interest in quality issues. Since then, quality management has evolved from a focus on the quality of a product or service output to overall organizational quality management. It has also expanded from technical and system considerations to attention now focused on an informed,[31,32] empowered, and engaged staff[33,34,35] as an essential component of quality. The underlying premise behind quality management is the continuous improvement of current state – not just 'assuring' quality or 'controlling' it.

Healthcare has learned about safety management from other industries, primarily aviation.[36] A unique feature of *safety management* compared with *quality management* is managing situations where things did not go as planned, especially situations where patients suffered, or nearly suffered, harm. Often the focus for collecting information about safety is unique because of its sensitive nature; therefore, sometimes society has put safeguards in place, such as those described in the *Alberta Evidence Act*[3] (Section 9), designed to increase the likelihood that people will volunteer information.

Many quality management and safety management models exist in non-healthcare industries; however, there is no comprehensive model that integrates these two approaches. There are concepts or principles[26,27,36,37,38,39,40,41] that are common among these various models that can be applied to healthcare systems:

- Customer focus/patient-centred
- Engaged staff
- Promotion of good governance and effective leadership
- Accountability with clear roles and responsibilities understood by everyone in the system
- Learning, innovation, and continuous improvement
- Information and analysis/measured performance
- Dedicated resources
- Continuous improvement
- Process and system approach
- Results/outcomes – customer, supplier, partners, human resource, financial
- Culture

Culture is a critical aspect of quality and safety management. "Culture – 'how we do things round here' – is both a function of governance and a reflection of the leadership, values, and drive of those in senior positions throughout the organization."[26] A culture that focuses on the quality of care and safety of patients develops in organizations that have a vision of continuous improvement, make decisions based on quality improvement principles, and make investments in infrastructure that supports quality management (e.g., education and training, policies, information systems, quality and safety and data analytics expertise). This requires and is supported by effective leadership and governance (as identified in the models above) with a strong, unified vision for quality and safety, a commitment to provide the necessary resources, and assurance of appropriate accountability for continuous improvement.[31,32,33,34,35,42,43]

Core functions of quality and safety management

Quality and safety management has three core functions: (1) measure/monitor/evaluate; (2) identify opportunities for improvement; and (3) improve the system. Figure 5 shows these three core functions, and illustrates how quality and safety management is a continuous, ongoing process.

Figure 5: Quality and safety management core functions

Measure/monitor/evaluate

Improvement starts with some form of measurement or evaluation following the axiom 'you manage what you measure'. Measurement creates the evidence for change when results are less than desired and helps to establish obtainable targets. Measurement also serves to create a baseline to which future system changes can be compared. Donabedian described measuring three characteristics of a system that could be assessed to reflect quality – the *outcomes* of care, the *processes* that are undertaken that produce the outcomes, and the system's *structure* – those elements that are in place to support the processes.[44] An indicator can be defined as a measure used over time to determine the performance of functions, processes, and outcomes. It can be used to assess the adherence to a standard, achievement of quality goals, or as a quantifiable value that can be used to evaluate performance over time, rather than just a 'snapshot' evaluation. Indicator monitoring often provides a valuable addition to standards-based evaluation, since indicators often focus on a few key structures, processes, or outcomes that represent an overall picture of quality of the organization.[45] Appropriate measures at different levels of the health system are required to enable improvement.[46]

Identify opportunities for improvement

Information from measuring/monitoring/evaluating can be used to identify opportunities to improve the quality of care and to identify safety hazards and hazardous situations. Because of the volume of information and opportunities for continuous improvement that exist in any system, healthcare organizations need to decide how they will use criteria-based decision making to determine which improvement activities will take priority.[27,37] Decisions made with the goal of mitigating the risk of harm

to patients are typically based on assessing the probability that a hazard or hazardous situation will lead to harm, the number of patients that could be affected and the severity of harm that could be expected.

Improve the system

Through the use of teams, employees are empowered to take action on the improvement opportunities using "practical methods and tools".[27,28,29] There are numerous quality improvement methodologies that can be employed to facilitate system redesign (see the literature review in Appendix IV). When safety is the focus of improvement efforts, a human factors-based approach is often undertaken to understand error-provoking conditions; with a view towards making structural changes to the system that address such conditions. Once improvement ideas have been tested and evaluated, the changes must be implemented.

Quality and safety management in continuing care

The success of any quality and safety management strategy for continuing care depends on the availability of scientifically sound evidence from a variety of sources addressing a broad range of dimensions of quality. It is not enough to judge the quality of care based on a single, disease-specific indicator in only one sector of the care continuum. Instead, different information sources should be used to address different aspects of quality across the continuum with a view to how the system as a whole functions, in addition to the performance of individual care settings. A quality and safety management (Q&SM) system should provide evidence about the experience of the population receiving services as a whole while also being capable of supporting the evaluation of care provided to specific clients. An organization's Q&SM system must inform decision-makers and regulators/funders about system performance with respect to quality concerns that affect large numbers of older people as well as rare but serious problems that may only affect a small number of people each year.

The three core functions (measure/monitor/evaluate; identify opportunities for improvement; and improve the system) apply to any Q&SM system. Within each of these three core functions are activities or elements, some of which are specific to the particular care area. For example, in continuing care there are various elements within the core function of measure/monitor/evaluate, such as continuous performance measurement (e.g., interRAI indicators), accreditation, audits, safety reporting, adverse event reviews, surveys, and patient concerns (Figure 6). These are discussed below.

Figure 6: Elements of quality and safety management as applied to continuing care

Accreditation

Accreditation is a formal external process used to assess and recognize "that a healthcare organization meets applicable pre-determined and published standards". "Accreditation standards are usually regarded as optimal and achievable", and are designed to improve the quality of healthcare organizations and encourage continuous improvement and organizational development.[45,47,48] Accreditation usually involves "measuring an organisation against other equivalent organisations, and providing feedback to the accredited organisation on progress towards quality goals and areas requiring greatest attention".[47]

Further research is required to determine the direct influence of accreditation on patient health outcomes. "While there is no conclusive evidence about the direct impact of accreditation on client outcomes", there is some indication that the accreditation process contributes to improving health outcomes.[49]

Surveys

Approaches to evaluating a client's experience receiving care have been developed over several decades. Earlier versions of these were referred to as 'patient satisfaction surveys'; however, more contemporary methods focus on the broader questions of the client's quality of life and his or her perceptions of the quality of care received. There are a number of problems with satisfaction-based questions, making them of limited use in healthcare settings.[50] For example, there may be a tendency to respond positively to avoid embarrassment or discomfort, and there is no clear reference standard against which individual service recipients can judge the care they received in a specific setting. In home care or long-term care

settings, it is substantially more difficult to judge expectations, given the lack of experience in other contexts. In addition, the sense of pressure to respond in socially desirable ways would be substantially higher in a healthcare setting than in the hospitality industry.

Current approaches to evaluating client's experiences in a particular healthcare setting tend to use specific questions about how they feel in the setting (e.g., perceived safety, sense of belonging, having meaningful things to do) and about how they feel they are treated by staff (e.g., staff respect privacy, respond in a timely manner). These approaches deal both with the quality of the person's life while receiving care, and the aspects of quality of care that overlap with quality of life.[51] For example, the sense that staff members respect a client's wishes could be thought of as relevant to both dimensions.

Surveys that address the client's experience have the advantage of capturing the unique, subjective experience of people receiving care. They also have important limitations that mean they can only provide a partial answer to questions related to quality in continuing care settings. The most important constraint is non-response bias.[52] People may be excluded from these surveys because they refuse to participate for a variety of reasons, including concerns about the confidentiality of their responses and potential repercussions if they give negative ratings. In addition, large portions of the continuing care population may be excluded due to cognitive or communication impairments. Although people without dementia may be able to respond to these surveys, it becomes increasingly difficult to obtain these evaluations from those with more severe cognitive impairment. It may be possible to obtain ratings about basic dimensions of quality of life (e.g., taste of food) but more abstract questions (e.g., being valued by others) may not be feasible in people with severe cognitive impairment. As a result, surveys related to care experience tend to focus on the healthier, cognitively intact population, and their experience cannot be assumed to reflect the experience of people with severe cognitive impairment.

Client concerns

Any service-providing organization, whether it is the hospitality industry, retailers, an educational system, or healthcare, must have a mechanism for receiving and responding to customer, client, or patient concerns. Quality indicators provide population-level evidence about health system performance, but service providers, health authorities, and governments are also accountable for care provided on a person-by-person basis. The ability to register concerns about services provided and to have that concern addressed is a basic expectation in Canadian society. Providing people in continuing care and their family members with a way to address their concerns is therefore an essential part of a quality and safety management system.

Concerns databases are relatively uninformative about the quality of care provided at the population level, however. For example, it is well known that there are individual and cultural differences in the likelihood of registering a complaint.[53] Counts of concerns registered do not provide information on the number of individuals who complained, do not indicate the rates of concerns in the eligible population, and may under-represent the views of less vocal subpopulations.

Continuous performance measures

The health of people receiving care has become a major focus of performance measurement systems across the health system, including in continuing care. The approach has been to use standardized quality indicators that deal with the factors expected to affect health, as well as direct measures of health outcomes. The indicators used typically relate to one or more of three types: (1) structure, (2) process, and (3) outcomes of care.[54,55] The ability to obtain measures of these dimensions depends on

the availability of valid, reliable, and standardized data sources for the populations of interest. Historically, it has been easiest to obtain structural measures and most difficult to obtain outcome measures.

Structural quality indicators deal with the types and amounts of resources available, the organization of services, and models of service delivery. For example, these may include the ratio of health professionals to the number of people who need their services (e.g., staffing levels in long-term care), the per capita expenditures in home care or long-term care, the availability of allied health professionals (e.g., access to rehabilitation), and approaches to determination of service eligibility. Structural indicators have been reasonably common over the last several decades because the data sources for their calculation have been readily available. These are only indirect determinants of health in the population, however, and their relationship to quality is often ambiguous. For example, some systematic reviews argue that long-term care staffing levels translate into variations in quality in terms of wound care, functional ability, and weight loss among residents.[56] Other, more recent, systematic reviews done outside the United States, however, suggest that the evidence linking staffing levels with quality of care is inconsistent and overly simplistic in its focus on numbers of staff alone.[57,58] Staff turnover, training, and how care is organized may be more important structural indicators to consider, but they are also more difficult to measure in a standardized way.

Process measures deal with how care is delivered and which services or interventions are provided.[55] This can include measures that deal with receiving specific treatments (e.g., rehabilitation services), the timing of the service (e.g., treatment within a given time period after needs are identified), and adherence to best-practice guidelines in care provision (e.g., avoidance of drugs known to be problematic for older people). Process measures are likely to be more closely linked to population health than structural measures because they deal with actual services or treatments provided to individuals. The evidence base for what is considered a 'best practice' often changes over time, however, and there are often differing views about what constitutes a "best practice".[59] This becomes even more challenging with an older population accessing continuing care services, who have more complex health conditions and who are often systematically excluded from most randomized clinical trials.[60]

Outcome measures deal with changes in a person's health or with health-related events that may be attributable to the quality of care provided.[55] These quality indicators are most relevant to the Institute for Healthcare Improvement's Triple Aim focus on improving the health of populations because they are direct measures of health rather than factors that may or may not be associated with variations in health. These kinds of measures have not been widely available previously, but the advent of standardized health assessment systems for widespread use in the continuum of care is now making it feasible to examine outcomes directly. For example, the interRAI family of assessment systems[61] provides comprehensive measures of the strengths, preferences, and needs of people in home care, long-term care, assisted living, and other continuing care settings. These instruments have been adopted by eight Canadian provinces and territories (including Alberta) and are supported nationally by the Canadian Institute of Health Information (CIHI). Two decades of research based on interRAI instruments has led to the development of outcome-based quality indicators for community and facility-based settings.[62,63,64,65,66,67]

There are two approaches that organizations or regulators can take when using performance measurement to 'drive' improvements in the health outcomes for clients. The first approach is to use collected data to set targets and compare performance over time internally. The second approach is to

use data to compare one organization with another. The main challenge faced by organizations seeking to use outcome measures to compare quality across service settings has been the issue of risk adjustment.[55,68] Given that the needs of clients within healthcare organizations vary substantially between organizations, the ability of outcome-based quality indicators to make fair comparisons has often been in question. It is an important limitation, because it may create disincentives for service providers to take on people who are more likely to decline in health or experience adverse events (e.g., falls). Risk adjustment uses statistical techniques to control for population differences in a way that attempts to 'level the playing field' in comparisons between organizations. The most current long-term care and home care indicators supported by CIHI and developed by interRAI use inclusion/exclusion criteria for quality indicators. For example, people who are at the end of life are excluded from some quality indicators because they will experience a clinical change that is substantially different from others in the service setting. As well, advanced statistical adjustment techniques are used, such as individual-level risk adjustment (which accounts for the characteristics of the person that make him or her more or less likely to experience the change or event) and organizational-level standardization of population-risk levels, similar to the approach used with age-standardized mortality rates.

interRAI

interRAI is a not-for-profit network of researchers and clinicians from 35 countries (including Canada) who collaborate in the development and application of comprehensive assessment systems to identify and respond to the strengths, preferences, and needs of vulnerable populations, including the elderly.[61,69] To date, eight Canadian provinces have adopted one or more of interRAI's assessment systems for home care, community support services, long-term care, palliative care, and mental health (inpatient and community) settings.

The primary purpose of interRAI assessments is to evaluate the strengths, preferences, and needs of the person assessed with the aim of developing a person-centred care plan in collaboration with the client and family members.[70,71] Each assessment provides a detailed overview of medical, functional, psychosocial, behavioural, and cognitive factors that can influence the client's quality of life. In addition to supporting care plan development, the assessment, when repeated over time, can be used to track outcomes of care – for example, depression,[72,73] cognitive function,[74] physical disability,[75] pain,[76] behaviour,[77] pressure ulcer risk,[78] and frailty.[79,80] These instruments can also be used at the individual level to match resources with a person's needs.

The two main management applications using aggregated interRAI data at the organizational level are funding and quality measurement. The Resource Utilization Groups (RUG) system uses interRAI data to classify long-term care and home care clients according to the level of resource needs based on their clinical characteristics.[81,82,83,84]

The use of interRAI assessment data to calculate quality indicators is extremely useful for performance improvement frameworks in continuing care. The most recent generation of quality indicators for nursing homes[85]and home care[65] used in CIHI's reporting system places a greater emphasis on outcome-based measures of improvements and decline in health. (See Appendix V and Appendix VI for a further description of the interRAI quality indicators, including historical development and the newly developed suite of interRAI assessment instruments.)

Public reporting on quality of continuing care

The Canadian Institute for Health Information (CIHI) supports national reporting systems for interRAI instruments as part of its bilateral agreement with provincial and territorial governments. CIHI's reporting systems ensure that the quality of interRAI data are high and they provide regular reports to individual organizations, regional and provincial governments, and partner organizations on the characteristics of populations services, quality of care, and resource use.

Variations in the rates of risk-adjusted quality indicators have been used to report publicly on the performance of continuing care by provincial[86] and national organizations.[87] The typical way to report on these indicators is to provide the rates of various quality indicators in specific organizations compared to a reference standard distribution (e.g., a provincial or national distribution of organization-level rates). The individual organization's standing in that distribution provides information about how well the organization performs relative to others. In Canada, Health Quality Ontario (HQO) and CIHI have collaborated to provide information on the quality of continuing care through publicly available websites.[86]

Providing the public with access to provider-level quality information can help with provincial quality improvement in a variety of ways. First, it provides a transparent and scientifically sound source of evidence about quality in the province (and in individual organizations) to any interested stakeholder, including members of the general public. Second, it provides a common benchmarking framework that individual organizations can use to set their own quality improvement goals. Third, it allows people needing care, and their family members, to make informed choices about the organizations from which they will seek continuing care services.

Identify and improve

Measuring quality through an approach that includes diverse measures of quality of life and quality of care from a variety of information sources is a fundamental first step for a quality and safety management system in continuing care. The act of measurement, however, is not an endpoint in itself. Instead, the evidence obtained through these measurement systems must translate into action that aims to improve performance where there is an opportunity to do so and to maintain excellence where it has been achieved.

An example of how quality indicators have been used to drive quality improvement is the Seniors Quality Leap Initiative (SQLI) undertaken by a collaborative network of Canadian (including Albertan) and U.S. long-term care facilities.[88] The SQLI consortium includes CIHI, Accreditation Canada, the Canadian Patient Safety Institute, Institute for Healthcare Improvement, and interRAI as collaborating partners. Participating facilities use a 12-indicator report based on interRAI quality indicators and resident experience surveys to examine their performance with outcome-based indicators relative to each other and relative to provincial, state, and national standards. These reports are used to launch collaborative interventions aimed at improving performance on priority indicators and subsequently to evaluate the success of those initiatives.

Because the assessment data are gathered on an ongoing basis as part of normal clinical practice, it is possible to evaluate the effect of improvement initiatives as they are implemented. The two current priorities for SQLI are to reduce the use of antipsychotic medications in clients who do not have a diagnosis associated with psychosis and to improve pain management.

For the Pleasant View Care Home in Saskatchewan, restraint use was the norm for managing dementia and falls. More than 50 per cent of residents experienced daily use of physical restraints, including trunk restraints and chairs that prevent rising. When staff at Pleasant View began to use interRAI Quality Indicators,[68] they quickly recognized that their restraint use exceeded national standards based on reports from the CIHI. A restraint-reduction initiative was launched as part of a quality improvement strategy at Pleasant View, and restraint use fell by 40 per cent, even with ongoing increases in the intensity of resident needs.

A similar change was experienced by staff and residents at Willow Lodge Home for Special Care in Nova Scotia. In this case, though, the quality concern related to high rates of depressive symptoms among residents. Almost 60 per cent of residents had depressive symptoms according to CIHI QI reports, and the majority of residents were involved in little or no activity in the home. A comprehensive strategy with a broad focus on medical, psychosocial, and environmental interventions was introduced, and the results were impressive: depression rates fell by half.

Internationally, Finland should be regarded as one of the best-practice leaders in national efforts to improve continuing care. Beginning in 2000, three Finnish cities (Helsinki, Kokkola, and Porvoo) launched a national initiative to improve the quality of long-term care in partnership with the Finnish Institute of Health and Welfare.[89] By 2010 the benchmarking initiative had enrolled 95 residential homes and health centres and now includes public and private sector organizations in most Finnish cities. As a result of this initiative the use of psychotropic medications dropped substantially (e.g., hypnotic use fell by more than 50 per cent) with no increase in rates of behavioural problems among residents in participating homes.

FINDINGS

The focus for this review was to determine how the Ministry of Health and AHS ensure the quality of continuing care services delivered directly by AHS and by providers under contract to AHS. Findings are presented according to the three core functions and the elements of quality and safety management as applied to continuing care, as shown in Figure 7, *below*.

Figure 7: Quality and safety management

Measure/monitor/evaluate

Accreditation

During the course of interviews, accreditation was described as a continuous improvement process and as the foundation of quality management. It was stated that accreditation looks beyond a simple checklist of whether a given factor is or is not present, for example, and looks at evidence and sustainability of practice. It was expressed that if service providers fully participate in accreditation, then the foundation for quality service is there; however, by itself, accreditation does not assure quality – it is an indicator of best practice and the service provider's process to achieve it.

The *Mandatory Accreditation in Alberta's Health System* ministerial directive requires that AHS take all necessary steps to ensure that hospital, nursing home, and other service providers under contract:[90]

- Participate in the accreditation processes undertaken by AHS.
- Undertake other accreditation activities as may be required by the Minister or AHS.
- Provide accreditation reports to AHS upon request.

- Advise and provide information on accreditation status, activities, and outcomes to AHS.

The AHS Community, Seniors, Addictions and Mental Health Department tracks the status of accreditation of all providers across the three streams of continuing care (home living, supportive living, and facility living).

The current Continuing Care Health Service Standards (CCHSS)[18] (Standard 1.22(b)) require that AHS obtain and maintain accreditation status from an appropriate accrediting organization as required by the Ministerial directive (e.g., Accreditation Canada, Commission on Accreditation of Rehabilitation Facilities). The proposed revisions to the CCHSS appear to have removed any reference to an accreditation requirement. A concern was voiced during interviews that this would leave the requirement for accreditation to be addressed solely through the service contract with AHS.

The AHS Master Services Agreement (MSA) Schedule C for home care providers[11] requires that if the home care service provider is not accredited by an approved accreditation organization, the provider will:

a) Have chosen an accrediting organization and have begun preparation for the Primer[ii] or equivalent by March 31, 2014.

b) Have successfully completed the Primer or equivalent by March 31, 2015.

c) Be accredited by December 31, 2016.

As part of the 2013 AHS request for proposal (RFP) process for home care services in the Edmonton and Calgary zones, there was a requirement for successful vendors to be accredited. AHS's goal was to have 100 per cent of contracted home care service providers accredited. Shortly after the awarding of the contracts from the RFP it was announced that some vendors that had lost their contract as a result of the RFP process would be offered new contracts. Not all of those vendors were accredited.

The Master Services Agreement Schedule C for Long Term Care and Supportive Living does not include a requirement for service providers to be accredited. In addition, it was identified that many legacy contracts (those 20 or more years old) that AHS 'inherited' from the former health regions, also exclude any requirement for accreditation. Currently, AHS wholly owned subsidiaries participate in the AHS accreditation process. As not every subsidiary site is visited with each accreditation survey, resulting in a lapse of years between survey visits, this is viewed by those interviewed as a 'watered down' version of the accreditation process.

There is considerable variability within and across the three continuing care service streams as to each service provider's accreditation status and the use of accreditation as a quality management tool. Table 5, provided by AHS, shows the percentage of continuing care programs accredited, current to March 31, 2013.

[ii] The Accreditation Primer helps organizations assess key areas of quality and safety and move to the Accreditation Canada Qmentum accreditation program. http://www.accreditation.ca/accreditation-primer

Table 5: Accreditation status, as of March 31, 2013

Program	Total number of sites/programs accredited	Total number of sites/programs	% Accredited
Home care sites	29	79	37%
Home care programs	45	52	87%
Adult day programs	2	49	4%
Contracted agencies	0	12	0%
Supportive living	31	136	23%
Facility living	126	174	72%
Contracted housing sites	0	36	0%
Personal care homes/Special care homes	0	92	0%
TOTAL	**233**	**630**	**37%**

Audits

Continuing care undergoes a number of different audits, which are done by different organizations and by different departments within organizations. The two main types of audits are those that assess compliance with two Ministry of Health standards – the Accommodation Standards and the Continuing Care Health Service Standards.

Accommodation Standards audits

The Accommodation Standards were originally established by the Ministry of Seniors. The Ministry of Health took over responsibility for them when the health portion of seniors' care was transferred to the Ministry of Health. Inspections and auditing to evaluate compliance with the Accommodation Standards are done by the Ministry's 17 licensing inspectors that cover the province. In order to operate, supportive living facilities must have a licence and long-term care facilities must have a certificate. Facilities must demonstrate compliance with the Accommodation Standards in order to obtain a new licence or certificate, or to renew a licence or certificate.

The inspections are announced and scheduled with the facility ahead of time. During the site visit, the licensing inspector reviews the 32 standards and the evidence gathered by the organization pertaining to the standards, tours the facility, and speaks to residents or family members about matters related to the Accommodation Standards. As part of the process, the licensing inspector reviews the facility's fire inspection report and, for supportive living sites, its environmental health inspection report. The fire inspection is conducted by the municipal fire department and the environmental health inspection is conducted by AHS.

At the end of the Accommodation Standards inspection, a report is completed by the licensing inspector and a copy is left with the facility. The report documents the facility's compliance or non-compliance with the standards. To address any areas of non-compliance identified during the inspection, a compliance action plan and associated timelines is developed. The inspection report is scanned and entered into a database in the Licensing and Compliance Branch of the Ministry, and is immediately

made available on the Ministry of Health website. Follow-up for non-compliance also occurs; this may involve the facility providing evidence to demonstrate that the area(s) of non-compliance has been addressed (e.g., documentation to demonstrate the call bell system has had periodic testing to ensure it is working properly), or may involve the licensing inspector doing another site visit (e.g., inspection to observe that flooring has been repaired). Information about the follow-up is documented, the designation of non-compliance is removed, a report is left with the facility, and the information is updated in the Ministry of Health database.

CCHSS audits

The current version of the CCHSS was established in 2008 and an amendment made in March 2013.[18] The Ministry of Health, through a collaborative process, is now working on a new version. Both the Ministry of Health and AHS conduct CHSS audits.

The Ministry has two full-time and one part-time (2.5 FTE) health compliance officers who conduct audits of continuing care facilities across the province. Although the CCHSS apply to all three streams of continuing care, the Ministry's health compliance officers have performed audits on long-term care and supportive living facilities only; to date no audits have been done by the Ministry within the home care stream. Currently, Ministry audits are done based on a 'risk assessment'. This means that facilities are audited if they have not been audited recently, if issues or non-compliance was identified in previous audits, if other types of audits or inspections have identified non-compliance, if there have been complaints or concerns raised in the media, or if an audit is requested by the Minister of Health. Although the decision to perform an audit is based on risk, all audits are scheduled with the facility. During the site visit, the CCHSS are used, documents are reviewed, observations are made of care processes (such as medication administration), a percentage of patient care records are examined, and staff are spoken to. The health compliance officer writes a report on the findings from the site visit, the facility is given a verbal debrief, and then a written report is provided later that describes the results of the audit according to each of the standards. If the facility was found to be non-compliant on any standard, a letter to that effect is sent, requesting a response within 60 days that outlines the action being taken to address the non-compliance. The action plan to address non-compliance is reviewed by the health compliance officer and compared to the standards. If the action plan is deemed to be acceptable, a written response is sent by the health compliance officer to the facility that removes the designation of non-compliance, and no follow-up in-person audit is conducted. Information from the audits and follow-up is tracked and filed by the Ministry.

Work is currently underway in the Ministry to have the audits from the CCHSS included in the same database used by the licensing inspectors who perform the Accommodation Standards audits. Unlike the results of Accommodation Standards audits, the results of the audits of the CCHSS are not posted on a public website; however, it was noted that results of an audit from a facility in Calgary were posted in December 2013 following significant media attention.

AHS conducts audits to the CCHSS in all three streams, including home care. Staff within each of the five operational zones of AHS conduct the audits, and the results of the audits are collated and tracked within the AHS Seniors Department. If deficiencies are noted during the audits, an action plan is created. As of December 31, 2013, AHS has implemented a standardized audit tool and staff were trained in using the tool, with the purpose of standardizing the audit process and decreasing variability among auditors. Interviewees identified that implementation of the tool was delayed due to the expected release of the

revised CCHSS. Prior to this, audits were done using different processes and tools by the five zones. The proportion of audits that have been completed in each of the three streams differs substantially by zone.

AHS provides a yearly report to the Ministry of Health on the audits it has conducted. Recently, there has been a concerted effort to improve the sharing of audit information between the Ministry of Health and AHS. Still, a number of interviewees commented about the variability in the audits, including variability among the AHS zones (i.e., audits in some zones found a substantially higher rate of fully compliant operators than audits within other zones), as well as variability between the audits done by the Ministry of Health and AHS.

Interviewees also commented that there are different philosophies of how to conduct audits. Some interviewees felt that auditors need to provide support and education to the facilities to assist them in becoming compliant to the standards; others felt that audits needed to be done using a more 'hands off' approach and that providing support and education needed to be done through other mechanisms. Many interviewees also commented on the duplication of having both the Ministry of Health and AHS conduct the same type of audits, as well as the 'burden' on the continuing care operators from the number of audits that they undergo. Many different opinions were heard about how to streamline the audit process and gain efficiencies, and whose role (Ministry of Health or AHS) it should be to conduct the CCHSS audits.

Additional audits and inspections

A number of interviewees from different organizations commented on the redundancies, inefficiencies, and 'burden' to the contracted providers because of the number of audits that the continuing care sector undergoes. In comparison, other sectors in the health system, such as hospitals, are audited less often. The concern of redundancy, inefficiency, and burden is not new; the issue has been identified in a number of reviews and reports, dating back to at least 2005.

In May 2005, the *Report of the Auditor General on Seniors Care and Programs* made a number of recommendations related to continuing care facilities. This included recommendations to: improve the systems for monitoring the compliance of long-term care facilities with the standards; update the Seniors' Lodges Standards and improve systems to monitor compliance.[91]

After the Auditor General's report, an MLA Task Force on Continuing Care Health Service and Accommodation Standards was struck, with a final report released in November 2005. In its report, the MLA Task Force made a number of recommendations, which included: (1) adopt the draft CCHSS and Accommodation Standards; (2) assess options for monitoring compliance with the CCHSS and Accommodation Standards, with the goal of having inspections done by one organization; (3) develop training and other supports as well as enforcement measures for providers who do not fully meet the standards.[92]

Subsequently, a review was conducted for the departments of Health and Wellness, and Seniors to inform them how to reduce overlap and duplication in the inspection and audit processes in continuing care. The stakeholder groups that were consulted identified the value of inspection and audit processes such as "protecting the health, safety and well-being of residents; providing consistent standards across the province; providing assurance to families and Albertans; fostering continuous improvement; ensuring accountability".[93] The report, which was completed in 2012, included a number of recommendations: (1) create a single, integrated group of inspections and auditors to deliver all health and accommodation-related inspections and audits of continuing care facilities; (2) review standards for

continuing care health and accommodation to make them clearer, more consistent, more aligned, easy to understand, and sensible; (3) improve training of inspectors and auditors to enhance consistency and collaboration in the delivery of inspections and audits; (4)establish an electronic database to reduce red tape and streamline inspection and audit processes; and (5) publicly report the results of all health-related and accommodation-related inspections and audits of all continuing care facilities in the province.

Until relatively recently, additional audits and inspections were also done in continuing care, which had historically contributed to the perception of redundancy and burden. Established in 1973, the Health Facilities Review Committee (HFRC), which reported to the Minister of Health, conducted unannounced, routine reviews of long-term care facilities and hospitals.[94] The HFRC was abolished in the fall of 2013. Continuing care facilities are also required to adhere to standards for infection prevention and control (IPC). Previously, separate audits and inspections to ensure compliance were completed. Currently, however, components of IPC are included in the CCHSS audits; separate IPC audits are no longer conducted.

At present, there is the potential for a continuing care facility to undergo six onsite audits or inspections within the same year. Along with audits to the CCHSS (done separately by the Ministry of Health and AHS) and the Accommodation Standards, continuing care facilities also must undergo regular fire inspections and public health inspections as part of the licensing process. The external accreditation process that many providers participate in includes another form of auditing.

Among the audits and standards there is a certain amount of overlap. For example, a supportive living site would have to meet all of the following standards, and would be assessed on its compliance, regarding bathing and water temperature. Conceivably, the supportive living site could have five separate audits/inspections related to bathing and water temperature as shown in Table 6.

Table 6: Audits and inspections related to bathing and water temperature

Continuing Care Health Service Standards	**1.21 (b)** Personal care of clients including oral care, continence management and safe bathing practices. ▪ The operators of long-term care and AHS-funded supportive living facilities shall ensure that their policies and processes set out the requirement that: ○ Residents are provided with the opportunity for bathing, at a minimum, twice a week by the method of his/her preference or choice and more frequently when determined by the client's care plan. ▪ For the purposes of this section, "bathing" includes tub baths, showers, full body sponge baths and bed baths.[18]
Accommodation Standards	**21(1)** An operator shall ensure that the temperature of flowing water provided for personal use in areas used by the residents does not exceed the maximum safe level established in the Alberta Building Code. **21(2)** An operator shall ensure that safe water temperatures for the personal use of residents are maintained through a) employee and resident training and education, b) proper maintenance and monitoring of equipment, and c) appropriate risk mitigation procedures. **21(3)** An operator shall ensure that all maintenance personnel and employees involved with the water system are sufficiently knowledgeable in the function and proper operation of the water gauges, water mixing valves and therapeutic tub controls, if any, to maintain safe water temperatures. **21(4)** Where a supportive living accommodation has one or more therapeutic tubs, the operator of the supportive living accommodation shall ensure that a sufficiently knowledgeable employee or service provider tests the temperature of the hot water flowing into each therapeutic tub each day prior to the first bath of the day and documents the temperature in a log book or on a log sheet kept in the tub room for that purpose.[19]
Environment Standards	▪ The maximum hot water temperature discharging from all fixtures that clients use or contact should be 49°C or less. Clinical staff should ensure a bathing/showering temperature of 38°C to 43°C. ▪ Hand washing basins that are accessible to residents should have a hot water temperature of 49°C or less. Regulatory enforcement will be considered if temperatures exceed 54°C. ▪ In resident-restricted areas such as the commercial kitchen or laundry areas, the hot water temperature maximums for residents do not apply. ▪ Residents must be adequately protected from injurious conditions such as radiators, hot water pipes or other heating devices. ▪ All personal hygiene items (brush, sponge, etc.) should not be left in the tub area. ▪ Extra linen should not be stored or present in tub rooms.[95]
Alberta Building Code	Safe water temperature as defined by the Alberta Building Code: ▪ "Where a hot water supply is required by Sentence 7.2.1.2.(4), equipment shall be installed that is capable of heating to at least 45°C but not above 60°C an adequate supply of service hot water for every dwelling unit." (2006, 7.2.6.1) ▪ "If the authority having jurisdiction deems it necessary to protect children, the elderly, or persons with disabilities or infirmities from burns, ... b) except as provided by the plumbing regulations made pursuant to the Safety Codes Act, the temperature of the water from faucets shall be limited to a maximum of 54°C." (2006, 7.2.6.7) Safe water temperature as defined by the National Plumbing Code: ▪ "3) All mixing valves supplying shower heads shall be of the pressure-balanced, thermostatic, or combination pressure-balanced/thermostatic type capable of a) maintaining a water outlet temperature that does not exceed 49°C and b)limiting thermal shock."(2005, 2.2.10.7) ▪ "4) The temperature of water discharging into a bathtub shall not exceed 49°C."(2005, 2.2.10.7)[96]
Accreditation Canada Standard	**16.10** The team implements a checking system for water temperature for resident bathing. Guidelines Processes and checking systems for high-risk care or service activities are important to resident safety. To identify high-risk activities the team reviews their services and uses this information to develop and implement checking systems to prevent and reduce risk of harm to residents.[97]

Safety reporting

At present, there are various mechanisms for reporting of safety information in continuing care in Alberta. This includes the mandatory reportable incident process, staff reporting, Protection for Persons in Care complaints, and reporting from patients and families (in the form of complaints and concerns).

Reportable incidents

In both the current and the latest revised version of the CCHSS, the Ministry of Health requires health authorities and operators to report 'reportable incidents' to the Ministry, following the process and guidelines set out by the Ministry of Health.[18,98] Incidents warranting mandatory reporting to the Ministry of Health are those where the following occurred:

1. Resident death or serious harm:
   - due to an error or omission in the provision of health services;
   - due to an assault or aggression;
   - due to equipment being in disrepair or used in an unsafe manner.
2. Client unaccounted for when their absence is outside the limits set out in their assessment, managed risk agreement, or care plan.
3. Unplanned activation of a contingency plan due to a staff disruption.[99]

The incident must also be either related to:

- health funded, meaning accommodations or services that receive funding from AHS (i.e., long-term care, designated supportive living, personal care homes, family care homes, home care and home living services); or
- non-health funded, which includes all other accommodations licensed under the *Supportive Living Accommodation Licensing Act* that are not funded by AHS (i.e., lodges, private assisted living, and group homes).[100]

The process for submitting a reportable incident was changed as of April 1, 2013. Prior to this change, contracted providers submitted a completed incident form to AHS, which then forwarded the information to the Ministry of Health. In the current process, the organization directly providing care (AHS if it is direct delivery or a contracted provider if under a contractual arrangement to AHS) completes a reportable incident form and submits it electronically. In the electronic submission process, the form is simultaneously sent to the Ministry of Health and to AHS.

When the report is received by the Ministry of Health it goes into an email inbox where it is reviewed by a complaints officer within the Standards Compliance and Licensing Branch. The information from the form is entered into a database. For those reports that are submitted under the Accommodation Standards, follow-up occurs within specified timelines based on the level of risk determined by the inspector:

- High risk – within one business day for incidents where residents are under current or imminent risk.
- Medium risk – within 10 business days for incidents where the issue and the underlying cause are still outstanding, but there is not an imminent risk to residents.
- Low risk – within 30 calendar days where the issue has been resolved, but further work may be required to address the underlying cause.

No follow-up occurs when issues and the underlying causes have been resolved. For those requiring follow-up, a Ministry of Health licensing inspector will contact the continuing care operator to gather more information about the event and what follow-up activities have occurred or are being planned.

For reportable incidents that are submitted under the CCHSS, the reports are submitted concurrently to AHS and the Ministry of Health. Each report is reviewed to determine the need for follow-up and to determine the need for an audit through a risk analysis. The Ministry only follows up on the reportable incidents related to the CCHSS that are considered to be high risk; that is, where there is an imminent or current risk to residents or a death, assault, or serious injury caused by error or omission. Follow-up may include contacting the operator or completing a CCHSS audit.

Information on the number of reports received and the number/percentage that receive follow-up by the Standards Compliance and Licensing Branch is tracked; however, no regular reports are created on the quality of care and patient safety information from the database for trending and further analysis.

In AHS, the electronic reportable incident forms are received initially by the Community, Seniors, Addiction & Mental Health Department. The form is shared with the AHS zone within two business days, where more information may be added and follow-up occurs. Information from the reportable incidents are entered into a spreadsheet for tracking. AHS receives a monthly log of reportable incidents from the Ministry of Health; the Ministry of Health and AHS logs are compared, and incident reports that do not meet the criteria are removed by AHS.

Protection for Persons in Care complaints

The *Protection for Persons in Care Act* "requires all publicly funded service providers to protect clients from abuse and prevent abuse from occurring, and requires all abuse to be reported to Protection for Persons in Care (PPC), the police or another regulatory body".[101] Individuals reporting an abuse to the Ministry of Health's PPC do so by calling a toll-free number. Reports of abuse are reviewed by a PPC complaints officer for thoroughness, additional information is gathered if required, and then a decision is made if further investigation is warranted.[101] Investigations can only be done by PPC if the care was provided by an organization receiving government funding. If the alleged abuse is a criminal offence, then it will be forwarded to the police. If the abuse involves a healthcare professional, it may also be referred to a health professional regulatory body.

A PPC investigation involves gathering information, conducting interviews, doing site visits, and reviewing records and other documents. After completion of an investigation, the director reviews the investigator's report, determines if the allegation is founded or unfounded, approves or rejects recommendations, and then outlines specific action required of the individual or service provider to prevent further abuse from happening.[101] An appeal process also exists. The service provider must respond to the decision and provide supporting documentation indicating compliance with the recommendations. Information about PPC investigated cases, including the reports and decisions, as well as statistical summaries on reporting, are posted on the Ministry of Health website.

The Ministry of Health shares PPC reports with AHS, which then enters the information into a log. The Ministry sends a yearly log of all the PPC reports received to AHS so that a comparison can be made to determine if reports were missed and to make necessary corrections. The chief executive officer (CEO) of AHS is copied on all PPC director decisions concerning AHS facilities or providers who are contracted by AHS. Information is then to flow from the CEO's office to the operational zone and the provincial Seniors Department. Some interviewees, however, stated that AHS does not always receive information

about PPC complaints from the Ministry of Health, or does not receive the reports soon enough to identify contracted providers that have problems with patient safety or quality of care. Interviewees described examples when AHS was not aware of allegations of abuse in contracted facilities until after they were reported in the media.

Incident reporting

The current CCHSS Standard 1.16 requires "processes to prevent, monitor, promptly respond to, and report any adverse events resulting from medication use" and Standard 1.2 requires "reviewing reportable incidents, near misses and other information to help prevent incidents from occurring in the future".[18] Obligations for contracted providers to share incident reporting information with AHS is dependent on the language in the contract. In the new master service agreement, there is a requirement for operators to share incident reporting information with AHS: "The Service Provider shall immediately report all significant safety events to AHS in sufficient detail necessary for AHS to fulfill any emergent responsibilities and the Service Provider shall review and investigate all complaints and incidents filed in relation to the Services provided by the Service Provider under this Service Schedule in accordance with AHS Policies".[102]

Organizations that are contracted by AHS to provide care may have their own internal reporting systems. Within AHS, when clients experience harm or a close call, AHS staff, volunteers, and physicians can submit an online report into the AHS Reporting and Learning System (RLS). Reports are coded and then tracked and 'trended'. Managers and advanced users are able to create trending reports for their area. The Quality & Healthcare Improvement Department prepares quarterly reports on the numbers of reports received and the themes. As well, different types of additional ad hoc reports can be created for trending and analysis of specific patient safety issues.

It is important to note that staff who are not employees of AHS (i.e., employees of an organization contracted to provide services), as well as patients and families, are not able to submit a Reporting and Learning System report directly into the AHS online system. Some interviewees commented that because the RLS only includes a portion of safety reports in continuing care, it is not seen as a good source of safety information.

Concerns reporting

The current CCHSS include a specific standard requiring a process for clients to raise concerns and to "provide a fair process for managing concerns/complaints and attempt in good faith to resolve concerns/complaints within a reasonable time".[18] The draft revised standards also recognize the importance of having a concerns/complaints process, requiring service providers to have a process in place for managing concerns, to share information on the concerns resolution process, and to provide information on external resolution processes for complaints/concerns.[98]

In Alberta, concerns from clients and families are received and managed through different mechanisms:

- Contracted care providers may receive concerns directly and manage them through their own internal processes. Information from individual concerns are not necessarily shared with AHS or by the contracted providers, unless it meets the Ministry of Health's requirements for a reportable incident.
- When care is provided directly by AHS, concerns from clients and/or families may come directly to the AHS care providers, case managers, or management, which provides a response. Clients

and families may also lodge a complaint through AHS' Patient Relations Department and a formal process will be followed.[103] Concerns that come to AHS through this formal process are entered into the Feedback and Concerns Tracking (FACT) database. Information in the database can be tracked and trended; as well, regular reports are generated from the database and shared with the leadership at the zone and executive level within AHS.

- Concerns may come from clients or families to the Ministry of Health or directly to the Health Minister. When this occurs, the Ministry of Health shares the information with AHS for follow-up and responds to the individual who lodged the complaint.
- Concerns about the conduct or competence of an individual healthcare provider can be made directly to the provider's professional regulatory body, in accordance with the *Health Professions Act*.[104]
- Patients and families may also send a formal concern to the Alberta Ombudsman. Legislated by Alberta's *Ombudsman's Act*, the Ombudsman "responds to complaints of unfair treatment by provincial government authorities, the patient concerns resolution process of Alberta Health Services, and designated professional organizations under the Health Professions Act...".[105]

Quality assurance reviews

The CCHSS require quality improvement and quality assurance systems to be in place, including processes to review "incidents, near misses and other information to help prevent incidents from occurring in the future".[18]

AHS has a quality assurance committee structure, which is approved by the AHS Board. These committees' activities, mainly conducting quality assurance reviews, are done under the protection of Section 9 of the *Alberta Evidence Act*. Staff from Quality & Healthcare Improvement support the quality assurance committees and assist with conducting quality assurance reviews. A process is followed for receiving and then accepting or rejecting recommendations from the quality assurance reviews. The recommendations are entered into a database after completion of the review; the status of the implementation of the recommendations is monitored, the database is updated, and a quarterly report is distributed to the quality assurance committees and AHS executive leadership.

Reviews may also be conducted by contracted providers. AHS would only be involved in these reviews if it was invited to participate by the contracted provider. Information from these reviews may or may not be shared with AHS; however, if it meets the criteria of a reportable incident, then communicating the action taken to address the safety problem with the Ministry of Health and AHS is required. From interviews, it was noted that the involvement of AHS in quality assurance reviews undertaken by contracted providers varies among the zones; some zones stated that the reviews were done in a partnership between AHS and the contracted provider, while others stated AHS would not be included in the review and would only receive a report of the provider's actions to address the problems.

Surveys

The current CCHSS (Standard 1.4 (e)) state that AHS shall conduct a survey of clients related to quality of care at least every two years, analyze the results, share results with service providers (including staff and clients), and respond to quality concerns that are identified through the survey.[18] The proposed revision to the standards would require that the service provider have a documented process for providing feedback on client services and that clients and families "have access to"[98] the process, but the administering of a client/family survey is not specified.

The MSA Section 5.7 requires, "As reasonably requested by AHS, the Service Provider shall participate in surveys of clients and families".[102] The MSA Schedule C for Supportive Living and Home Care quality assurance sections state that the service provider shall "ensure that SL clients are given the opportunity to evaluate or comment on the service", "make available its satisfaction surveys to all SL clients", and "distribute and retrieve satisfaction surveys on a voluntary and confidential basis".[11,106] The Long Term Care Schedule C requires that the Service Provider "submit documented evidence of a patient satisfaction program, including documented evidence of ... Client satisfaction surveys",[107] the format of which can be determined by the Service Provider.

Various client/family satisfaction surveys that were either conducted by AHS at a provincial level, AHS zones, or individual contracted service providers for the home care stream were reviewed. Although the topic areas addressed in the surveys were somewhat similar, they were quite varied in the specific questions asked, the respondent targeted (client and/or family), and the structure of the questionnaire itself. As such, no two questionnaires are alike and so this does not allow any opportunity to compare among sites or across or among zones, or to aggregate data at a provincial level for reporting and quality improvement purposes beyond the individual site level. From the interviews it was apparent that the measurement of client satisfaction was an important factor in quality management and it was acknowledged that it required more attention.

As part of a collaborative effort led by the HQCA and including the former health regions (now AHS) and the Ministry of Health, province-wide surveys were initiated in the three streams of continuing care. Beginning in 2007, the HQCA conducted its first survey of residents and families in long-term care centres across the province. The family survey was repeated in 2010 and data collection for a third survey was initiated in March of 2014. The results of the surveys were shared with long-term care stakeholders across the province and each participating site received site-specific results. The results were shared with residents and families in an aggregated provincial-level report.[108] Service providers are able to compare their specific results with zone and provincial results.

In late 2013, the first provincial survey of residents and families in supportive living environments (SL3, SL4, and SL4D) was initiated by the HQCA. These results are scheduled for public release in the fall of 2014. In its 2014/15 business plan, the HQCA will begin surveying clients receiving home care services across the province.

Continuous performance measurement

Each organization, including the Ministry of Health and AHS, has established processes for collecting, monitoring, and reporting quality improvement information at a site, organization (provider), zone, provincial, and even national level.

In the current CCHSS, Standard 1.22 requires the quality improvement program to include "monitoring client outcomes and comparing them with evidence-based practice" and that quality indicators be used to "improve services and achieve quality outcomes".[18] The proposed revisions to the CCHSS only require that service providers "submit information including where applicable RAI data and other quality indicator data as required by Alberta Health".[98] The use of this data for quality improvement (QI) purposes is no longer specified in the proposed revisions.

Schedule C of the MSA for Long Term Care and Supportive Living require that AHS[106,107] "shall evaluate the Service Provider on an on-going basis using AHS' generated key service indicators to identify quality improvement opportunities" and "service quality standards and indicators will continue to be developed, monitored, reviewed and updated by AHS on a regular basis in collaboration with the Service Provider". The provider must also monitor and assess care standards and the effectiveness of the services provided to determine possible improvements that will enhance the lifestyle and environment of the clients. These improvements must be shared with AHS.

For long-term care, the service provider is required to collect and submit specific performance indicator data, including interRAI data, as required by AHS and in accordance with guidelines set out by the Ministry of Health.

Schedule C of the MSA for Home Care[11] specifies a list and frequency of reporting of "Quality" indicators that include, survey results, accreditation results, number of medication incidents and witnessed falls, and staff turnover.

The Ministry of Health reports annually on the number of people waiting in hospital beds and in the community for continuing care. This performance measure monitors and reports on progress toward reducing the number of people waiting in either acute/sub-acute care or in the community for a publicly funded continuing care living option. The stated intention is to provide all Albertans requiring continuing care with access to appropriate options within 30 days.[109]

AHS reports publicly on 16 performance measures that reflect key areas within the health system it believes are important to Albertans.[110] Two of these measures reflect on specific performance aspects of the continuing care system:

- **Satisfaction with long-term care:** The percentage of families of long-term care residents who rated the overall care as 8, 9, or 10, where 0 is the worst possible care and 10 is the best. In the 2010/11 AHS survey, 73 per cent of families rated the care as 8, 9, or 10. The target for this measure is 78 per cent by 2015/16. AHS states that measuring family satisfaction with the care that is being delivered to residents is an important component of managing the quality of Alberta's long-term care services.[110]
- **Continuing care placement:** The percentage of clients admitted to a continuing care option (supportive living or long-term care) within 30 days of the date they are assessed and approved for placement. In 2012/13, 67 per cent of clients were admitted within 30 days of being assessed and approved. The targets for this measure are 68 per cent by 2014/15 and 70 per

> cent by 2015/16. This includes patients assessed and approved and waiting in hospital or the community. AHS believes that timely access to continuing care (supportive living or long-term care) ensures higher quality of life for seniors.[110]

The AHS Seniors Department has developed a dashboard of measures that are refreshed monthly. The measures were agreed upon by the zones and the Seniors Health Strategic Clinical Network. This dashboard is available to AHS staff but not to the contracted service providers. The dashboard contains the following measures:[111]

- Number of home care clients reported quarterly by zone and province.
- Number waiting for supportive living (SL) and long-term care (LTC), optimal and assessed by month.
- Number LTC and SL living spaces by 1,000 needs-weighted population by zone (ratio of spaces provided/1,000 needs-weighted population).
- Number waiting in acute/sub-acute and community for LTC or SL (broken down), monthly and zone.
- Beds (spaces) available (LTC, SL) by zone.
- Assessed and waiting in acute care by acute care site.
- Caregiver distress.
- Depression rating scale.
- Pain scale.

Through interviews and a review of documents it became apparent that data collection, analysis, and reporting of continuing care metrics varies greatly across the three continuing care streams, service provider organizations, and AHS zones. Data and information are presented in various forms and in various degrees of detail across the streams, provider organizations, and zones to support local information and reporting needs. This variability is also due to the inconsistency and availability of information systems from the legacy health regions, and the degree to which these systems have been integrated to support the provision of continuing care services and therefore quality monitoring. For example, home care program statistics provided to the HQCA came from various sources – STATIT, DIMR, and Zone Weekly Visits Report. The interRAI contact assessment has only been implemented in the North, Edmonton, and part of the Central Zone. The Calgary Zone would need to incorporate assessment data into the PARIS system, which could take several years for full implementation. This limits the analysis and reporting of wait time data across the province. The South Zone 'lost' historical data when the Meditech system software was changed.

Current AHS reporting includes utilization statistics such as admissions, discharges, and transfers to the three service streams; types of clients and services provided; missed visits; caseload measures; and emergency department and hospital visits. Other metrics include incident reports, client/family survey results, workforce measures (turnover, etc.), complaints, and only some interRAI measures.

Interviewees identified a disparity throughout the province in the resources available to support the analysis and reporting of performance information. It was noted that variability exists both within service provider organizations and among AHS zones.

As part of the government's results-based budgeting process in September 2013, AHS identified numerous issues regarding continuing care information systems that support what the HQCA heard from interviewees and assessed from the documentation received. AHS identified that in order to support better patient experience and care outcomes "system level outcomes will be more readily available with the completion of the Alberta Continuing Care Information System (ACCIS)".[112] The document goes on to state that "current performance measures are reviewed on a zone by zone basis however there is limited review at the provincial level...Quarterly reports of provincial data are limited, the only available and reliable measure used to indicate performance is unique home care counts, however this does not provide information on the quality or even type of services being provided". It was also identified that "the introduction of the ACCIS database will increase opportunities to examine quality measures from a population perspective, driving future quality improvement initiatives.[112] In the document it states that the "IT infrastructure is immature and not robust across the province".

According to the Ministry of Health, the ACCIS has been functional since October 2010 with the ability to capture interRAI information. System-level reporting, interRAI outcome indicator calculations, and flow of data to CIHI has been an ongoing process, with most of this functionality available currently. Long-term care interRAI information as of January 2010 and onwards has been submitted to ACCIS, and as of March 2014 has been submitted to CIHI. All long-term care service providers are currently submitting data to ACCIS as of the most recent fiscal quarter; AHS ensures that providers are current with their submissions. For interRAI HC information, work is ongoing to collect historical data for clients who were active as of April 2011 and onwards; AHS and zones are currently working on submitting data to ACCIS from 2011/12 and early 2012/13.

RAI quality indicators

The CCHSS (Standard 1.8) state that "continuing care clients are assessed for health service needs using a standardized comprehensive assessment tool".[18]

Prior to 2010, Alberta began implementation of interRAI's Resident Assessment Instrument used in long-term care (RAI 2.0), and the Resident Assessment Instrument for Home Care used also in supportive living (RAI-HC).[113]

In 2012, as part of the *Quality Enhancement in Continuing Care Project – RAI Quality Review Project* it was identified that there was no provincial review mechanism in place to validate the structure, business rules, and outcomes of the interRAI assessment process. The review stated that a provincial review process was needed to increase confidence in the reliability and validity of the interRAI assessment data, and that coding of the interRAI assessments should be compliant with the definitions as outlined in the respective CIHI Resident Assessment Instrument user manuals. The demonstration project would allow AHS Seniors to develop standardized interRAI review approaches and tools for consistent application, and to emphasize accurate interRAI coding to increase confidence in Alberta interRAI data. The Alberta data are used for decision-making at the clinical, operational, and strategic levels of AHS and the Ministry of Health.[114] This project is currently being implemented across the province.

Interviewees identified that the interRAI instruments are in use to varying degrees across the province; that is, the interRAI instrument used in long-term care is further ahead than the interRAI instrument used in home care (interRAI HC). Therefore, the reporting and use of the interRAI data, including the interRAI quality indicators, also varies. For example, the Edmonton Zone has just in the past year started using the interRAI HC for assessment. It now needs to train the case managers to use the tool for care

planning. The next step will be using the data for reporting quality indicators and for monitoring and improving the quality of care. It was also identified that reports are not always available or used by frontline staff. The North Zone has two small teams (one for home care and one for long-term care) to support education, data quality, and analysis and monitoring of quality indicators. The Central Zone uses the clinical assessment protocols for LTC resident care planning purposes but does not yet use them for home care client care planning. In addition, site managers pull interRAI long-term care indicators and review data at the site level and compared to other sites in the zone.

Contract monitoring

Continuing care contracts are not yet standardized across the province as some are 'legacy' contracts that AHS inherited from previous regional health authorities and from the Ministry of Health, resulting in variable contract accountabilities. AHS is in the process of moving all new and existing service providers towards a master services agreement (MSA) and service schedules that will be consistent across the province. Interviewees identified that moving legacy contracts to the new MSA has been difficult and is taking longer than what was originally expected. Within the three streams, long-term care has the smallest proportion of contracted providers on the standardized MSA (see Table 7).

Table 7: Continuing care sites (per cent) on legacy contracts and standardized MSA as of April 2014

	Legacy	MSA
Long-term care	83 (93%)	9 (7%)
Supportive living	86 (38%)	206 (62%)
Home care	26 (17%)	38 (83%)
Home care day programs	7 (22%)	30 (78%)

The master services agreement: (1) clarifies the rights and obligations with respect to continuing care service provision, (2) governs the relationship between AHS and the service provider, and (3) contains the general terms and conditions governing the contractual relationship. The schedules, which are specific to the three streams, provide additional and specific details about the services that are to be provided, as well as additional requirements related to quality and safety, such as adherence to the CCHSS, becoming accredited by an approved accreditation organization, reporting of incidents, quality assurance processes, and reporting on performance results.[11,106,107] A service provider that has contracts in various zones, which may include a combination of legacy and new MSA contracts, may be held to different accountabilities on the same matter.

As explained by interviewees, the contract is a 'tool' that enables the strategies, policies, and reporting to occur, and enables AHS to hold the contracted providers accountable. AHS monitors the providers' compliance with obligations outlined in the contract. For example, this includes monitoring compliance with the terms in the contract, conducting financial audits, and reviewing the performance information that is required by contract to be provided to AHS. Different departments within AHS are responsible for these various oversight and monitoring activities – the five operational zones, Business Advisory Services, and Contract Procurement & Supply Management.

Each zone is responsible for monitoring adherence to the clinical components of the contract. Yet, it was identified in interviews that the degree of scrutiny and the level of monitoring of contractual compliance varied across zones. The leadership in at least one of the zones commented that since AHS has been

established, the zone has not been involved in the contract process and does not even have copies of the contracts.

The Business Advisory Support Department performs financial audits, accessing the financial information reporting measurement system (FIRMS) database, which is used by both the Ministry of Health and AHS and contains financial information on contracted providers of long-term care facilities. The intent is to expand the number of organizations that are included in the FIRMS database; AHS long-term care facilities will soon be included in this database. FIRMS will also be expanded to include supportive living and eventually home care. For those providers that are not entered into the FIRMS database, financial templates are completed by the contracted providers, which are then reviewed by AHS. The financial audit includes a review of financial information to evaluate the 'financial health' of the contracted organization and also to ensure fiscal accountability. For example, the number of professional and non-professional care hours that are provided, categorized by different health providers, are reviewed and compared to the contract requirements. If it is found that the number of hours that have been contracted and paid for by AHS are not being delivered by the contracted provider, AHS can recover the funding for this. The financial audits are more than just prudent financial practice, however. Contracted providers that are not providing the number of patient-care hours that they have been contracted to provide, or that are providing the correct number of hours but are doing so through an inappropriate mix of health providers (i.e., more healthcare aide hours than professional nursing hours), may not be delivering a high-quality service to their clients. This financial information is shared with the zone operational leadership, as well as with a provincial steering committee, to be used along with other quality measures in AHS' monitoring of the quality of services provided.

Along with leading the establishment of agreements, the Contract Procurement & Supply Management Department (CPSM) assesses aspects of contract compliance, such as determining if insurance requirements were met. As well, CPSM is aware of all the contract requirements, and thus would involve additional departments and individuals as required.

In addition to these distinct groups within AHS that are monitoring contractual compliance, AHS has a committee called the Major Contracts Oversight Committee (MCOC). As a standing committee of AHS' Executive Leadership Team (ELT), this committee is mandated "to provide guidance and recommendations to the ELT on matters of contract oversight that may affect AHS strategies and objectives, while ensuring that any contracting activity creates best value for AHS without compromising on quality of care".[115] As part of its mandate to provide contract oversight advice to the ELT, the MCOC provides direction and guidance on contracted services that are not delivering desired results or meeting expectations and thus require intervention. The MCOC also receives and reviews contract reporting information, such as reconciled payments against contracts, as well as some performance metrics.

Interviewees stated that AHS recognizes improvements are needed in contract compliance monitoring and oversight. The provincial Community, Seniors, Addictions & Mental Health Department does not currently have responsibility for contract compliance monitoring and oversight. Interviewees commented that the intention is that this department will take on more responsibility for aspects of risk management and quality management in continuing care, including a role in contract compliance monitoring and oversight. As well, AHS has recently developed a Contract Monitoring Framework, which outlines performance monitoring and assessment; evaluation, risk, and response; and improvement activities, such as corrective and preventive action.[116]

Identify opportunities to improve the system

Across AHS there are different committees with mandates to review the available quality and safety information, and then identify and prioritize opportunities to make improvements. This includes various quality councils and committees that exist within the three continuing care streams and in and across the five zones. The membership for these committees may include representation from the zones; Community, Seniors, Addictions & Mental Health; Quality & Healthcare Improvement; CPSM; Infection Prevention and Control; and service provider organizations. Most interviewees stated that decisions on which improvement initiatives to pursue were often made through committee discussion and consensus. AHS also has a formalized quality assurance committee structure; the mandate of these quality assurance committees is to perform quality assurance activities as defined by the *Alberta Evidence Act*.

Improve the system

The current CCHSS are based on a set of principles, one of which is quality improvement. The CCHSS quality improvement Standard 1.22[18] requires that quality improvement (QI) programs are established to regularly evaluate and improve continuing care health services. The program components include, but are not limited to:

- Using quality indicators to improve services and achieve quality outcomes.
- Developing, implementing, and overseeing QI strategies and action plans.

The standards compliance audit tool used by AHS auditors determines compliance with this standard based on evidence of a service provider policy or process. Interviews with clients, families, or staff are not a requirement of the auditing process for this standard. It is not clear what the process is to verify that performance measures are used to identify opportunities for improvement (e.g., client outcomes measures, client/family surveys), or what the process is for developing, implementing, and overseeing QI strategies and action plans.[117]

The draft revised standards lack a specific standard that speaks to QI;[98] however, Standard 20.0 (Information Reporting and Review) states that the service provider shall have a documented QI program and policies and timelines in place to evaluate and improve healthcare services. The QI program components, such as the requirement to develop, implement, and oversee QI strategies and action plans, are either incorporated into other standards or are no longer specified.

In the SL and LTC Master Services Agreement Schedule C – "The Facility Supervisor/Manager's duties include, but are not limited to the direction and coordination of quality improvement programs to regularly evaluate and improve continuing care health services". The contract goes on to state that "AHS shall evaluate the Service Provider on an on-going basis using AHS-generated key service indicators to identify quality improvement opportunities".[106,107] In the home care Schedule C the only reference to quality improvement is to report on the accreditation status.

The AHS Seniors Department is responsible for collaborating with the zones to identify and gain consensus on best practice, support the zones to adopt those practices, and develop standardized practice and processes. This includes, for example, the standardized CCHSS audit tool, standardized education and process for conducting interRAI assessments, and development of the healthcare aide competency assessment profile. The AHS Seniors Department is the liaison with the Ministry of Health

for "setting operational policy that aligns with and flows from the Ministry's directional policy."[98] Within the past year and a half, AHS Community, Seniors, Addictions & Mental Health Department has implemented a Quality Improvement, Policy, and Evaluation (QIPE) team. This team provides resources in the areas of quality outcomes, informatics, measurement, and project support services for the department and the zones.

Zones participate in both local and provincial quality improvement initiatives, for example:

- Quality Enhancement in Continuing Care Project – RAI Quality Review.[114]
- Appropriate use of anti-psychotic drugs with the Seniors Health Strategic Clinical Network.
- Home care redesign strategic plan.[118]
- AHS Alberta Improvement Way (AIW) pilot project in the Calgary Zone on home care missed visits. Through a collaborative process a 50 per cent reduction in missed visits was set as the project goal. This process is being rolled out to all home care providers in the Calgary Zone and will be shared provincially.
- Destination Home, which targets community-based clients at risk for institutionalization to maximize their potential to remain in their home if safely able to do so. The goal is to facilitate safe discharge of patients – with comprehensive home care and community supports – while awaiting assessment for continuing care.[119]
- Path to Home, a provincial discharge model to improve transitions to community care and reduce assessed and waiting times.[119]

As part of the patient-care-based funding model, 0.02 per cent of funding is allocated to operators for QI purposes based on interRAI data and specifically identified QI initiatives. In addition, some QI or innovation initiatives are funded through a Ministry of Health restricted grant. Interviewees expressed concern that although the projects were worthwhile the one-time grants did not provide for ongoing funds to sustain the project beyond the end of the restricted funding grant (e.g., Destination Home and Quality Enhancement in Continuing Care Project-RAI Quality Review Project).

Supporting quality and safety – education, policies, and guidelines

Education

In the proposed revision to the CCHSS, specific standards were included that require continuing care staff be provided training.[98] Training on a number of quality and safety topics must be provided within six months of someone being hired and after any existing guidelines, standard, legislation, or regulation is revised. A list of other topic areas is included for which training must be provided within a year of hire and every two years ongoing. Annually, the provider is required to ensure staff are aware of policies and procedures.

AHS has a small provincial team, called the Quality and Safety Education Team, whose job is to provide and support education and training on quality and safety for the organization. Examples of courses include the basics of patient safety, quality improvement methodology, disclosing harm to patients and families, and leadership in quality. There has been a movement towards making courses available online; however, contracted providers cannot access the internal AHS website on which these educational resources exist. AHS is using other mechanisms to support sharing of information and

providing education to providers who are not direct employees of AHS; for example, an external website was set up for a training project in medication reconciliation.

Although the focus of the AHS' Quality and Safety Education Team's activities has been to provide education to AHS staff and physicians, in December 2011 a grant from the Ministry of Health was secured that enabled AHS support for training of contracted continuing care providers. One of four deliverables was to provide targeted education and coaching to interested contracted service providers to improve baseline knowledge regarding patient safety principles (Fundamentals of Patient Safety) and quality improvement methodology (AHS Improvement Way – AIW). Training opportunities were provided between April 1, 2012 and March 31, 2013. In total 136 people were trained; 104 attended the Fundamentals of Patient Safety course, and 32 attended the Alberta Health Services Improvement Way course. Targeted education continued to be offered to continuing care contracted providers in the 2013/14 year.

Policies and guidelines

AHS has established two policies and an associated procedure that are specific to patient safety, which are applicable to continuing care:

- A policy and a procedure on *Disclosure of Harm*.[120,121] Harm is defined as "an unexpected outcome for the patient, resulting from the care and/or services provided, that negatively affects the patient's health and/or quality of life".[120] This policy describes AHS' commitment to open and honest communication between health professionals and patients and families; the requirement to disclose harm, any risk of potential future harm, and whether there is any change in care or monitoring; and the discretion to have a disclosure conversation with the patient/family in cases where there was a close call, based on benefit to the patient in knowing or wanting to know.
- A policy on *Reporting of Clinical Adverse Events, Close Calls and Hazards*.[122] The policy recognizes that reporting of adverse events, close calls, and hazards is important for learning and improving the safety of the health system, and that the participation of staff and medical staff in reporting is key to developing a just and trusting culture. "The reporting and learning system is a voluntary system of internal reporting that plays an important role in supporting a culture of safety by ensuring that locally-identified adverse events, close calls and hazards are reviewed individually or in aggregate and/or trended and shared for the purpose of organizational learning".[122]

In addition to the above procedure and policies, a practice support guideline called the *Immediate and Ongoing Management of Clinically Serious Adverse Events* has also been developed by AHS.[123] The intent of this guideline is to describe the roles and responsibilities of staff, physicians, and administrative leaders and the actions to be taken when a clinically serious adverse event occurs. A number of staff throughout AHS have received training in disclosure, and, along with staff from Quality & Healthcare Improvement, are a resource to others who undertake disclosure conversations with patients and families.

A final note

Despite the many continuing care quality and safety management elements and tools that have been described such as accreditation, standards audits, safety reporting, continuous performance measures,

and surveys, none of these alone can assure quality, nor can they provide the real-time, day-to-day monitoring of quality and safety provided by those at the frontline of care delivery. These 'eyes-on-the-ground' are a critical component of quality and safety management. In the home care and supportive living streams AHS, through the case manager, has the ability to monitor on a day-to-day basis. This is not the case in long-term care, in which AHS must rely on the service provider for notification, as per the CCHSS and/or contract provisions, when quality and safety issues arise.

ISSUES, ANALYSIS, RECOMMENDATIONS, AND REQUIRED ACTIONS

Three main areas were identified to improve the management of quality and safety in Alberta's continuing care system. The first area relates to AHS contract management and oversight of contracted providers. The second area involves strengthening core functions of quality and safety management in continuing care. The third addresses clarification of roles, responsibilities, and accountabilities for quality and safety management in continuing care.

Contracts

Issue

Due to variability in the continuing care contracts across the province, as well as lack of clarity for contract oversight, the contracts cannot be fully utilized as a tool to support AHS oversight of quality and safety management of contracted providers.

Analysis

Continuing care contracts are not yet standardized across the province, as some are legacy contracts that AHS inherited from previous regional health authorities and from the Ministry of Health, resulting in variable contract accountabilities. AHS is in the process of moving all new and existing service providers towards a master services agreement (MSA) and service schedules that will be consistent across the province; however, moving legacy contracts to the new MSA has been difficult and is taking longer than originally expected. Within the three streams, long-term care has the smallest proportion of contracted providers on the standardized MSA.

Given that a significant proportion of services in continuing care are provided through a contractual arrangement with external providers, having a standardized contract (MSA) is important for supporting quality and safety management across continuing care. The contract is an important oversight tool; it holds contracted service providers accountable for reporting and performing quality improvement and quality assurance activities. AHS monitors the providers' compliance with obligations outlined in the contract, conducts financial audits, and reviews the performance information.

Currently, responsibility for monitoring compliance to continuing care contracts is held in various AHS departments, resulting in an 'everybody is responsible' situation. The risk in this kind of approach is that 'nobody is responsible' as it is believed that responsibility lies elsewhere. Each zone is responsible for monitoring adherence to the clinical components of the contract, although it was identified that the degree of scrutiny and the level of monitoring of contractual compliance varies across zones.

Business Advisory Support performs financial audits. Contract Procurement & Supply Management assesses some aspects of contract compliance (i.e., determining if insurance requirements were met) and is aware of all the contract requirements, and thus would involve additional departments and individuals as required.

When contracted providers are not delivering desired results or meeting contract expectations, guidance can be sought from a standing committee of AHS' Executive Leadership Team (the Major Contracts Oversight Committee). However, the issues must first be identified and brought to the committee's attention. Having different departments across AHS responsible for various aspects of contract compliance monitoring and oversight could create situations in which it is unclear who is

ultimately responsible to take action when quality and safety issues arise. AHS has recently developed a Contract Monitoring Framework, which outlines performance monitoring and assessment; evaluation, risk, and response; and improvement activities, such as corrective and preventive action.

Recommendation 1

AHS develop a plan, with timeframes, to move all legacy continuing care contracts over to the standardized master services agreement.

Recommendation 2

AHS make explicit where the responsibility and accountability for continuing care contract compliance monitoring and oversight resides.

Audits and accreditation

Issue

The current auditing processes in continuing care result in redundancies and inefficiencies at the provider, health authority, and ministry levels.

Analysis

Continuing care providers are audited on their compliance with the Accommodation Standards by inspectors in the Ministry of Health; these audits occur as part of the regular licensing process, as do fire inspections (conducted by the municipal fire department) and public health inspections (conducted by AHS). Continuing care providers are also audited on their compliance with the CCHSS; these audits are done by both the Ministry of Health (frequency determined by risk) and AHS (by staff within each of the five operational zones, following a predetermined schedule). Finally, the external accreditation process that many providers participate in includes another form of auditing. Together, these result in the potential for six onsite audits or inspections within the same year. In addition, the content of the different audits and standards often overlap, meaning that providers are assessed on the same item, such as water temperature, through each of these different processes.

These redundancies, inefficiencies, and 'burden' of audits that the continuing care sector is exposed to is not new; the issue has been identified previously in government reviews and reports.

In addition to redundancy, other issues are evident:

- One of the problems with having different groups and numerous individuals conducting audits is the inevitable variability and the potential of poor inter-rater reliability. Many commented on the differences between the CCHSS audit results conducted by the Ministry and by AHS. Differences are also seen across the AHS zones. Recently, AHS has taken steps to decrease the variability and improve the inter-rater reliability of the CCHSS audits by creating a standardized audit tool and standardized training for auditors.
- Differing views were heard on how to improve the process, which organization (Ministry of Health or AHS) should be responsible for the audits, and how audits can be approached. It was suggested that to be meaningful, audits need to be conducted in an objective, 'policing' way, or using a more collaborative, coaching approach.

- While the CCHSS apply to all three care continuing care streams, the Ministry's focus has been predominantly on facilities, and to date there have been no audits completed in home care. Within AHS, the proportion of audits done in each of the three streams varies substantially across the five zones.
- Until relatively recently, CCHSS audit results were not shared between the Ministry of Health and AHS. While the results of the Accommodation Standards audits are available to the public on the Ministry of Health website, the results of the CCHSS audits are not.
- The CCHSS quality improvement Standard 1.22 requires that quality improvement (QI) programs are established to regularly evaluate and improve continuing care health services. The program components include, but are not limited to: (1) using quality indicators to improve services and achieve quality outcomes; and (2) developing, implementing, and overseeing QI strategies and action plans.[18] The standards compliance audit tool used by AHS auditors determines compliance with this standard based on evidence of a service provider policy or process; interviews with clients, families, or staff are not a requirement of the auditing process for this standard.[17] It is not clear what the process is to verify that performance measures are used to identify opportunities for improvement, or what the process is for developing, implementing, and overseeing QI strategies and action plans.
- There is considerable variability within and across the three continuing care service streams as to each service provider's accreditation status and the use and requirement of accreditation as a quality management tool by AHS.
- Considerable emphasis has been placed on monitoring compliance with standards in continuing care as a mechanism to assess for and assure quality. While monitoring for standards compliance is an important component of assessing quality, it is only one mechanism. Undergoing an audit to a set of standards once every two years, or even once a year, should not be relied on as the sole mechanism for identifying quality issues in continuing care. It is one source of information about quality, and it needs to be assessed along with information from other sources, such as performance metrics, client/family experience, and safety information to gain a complete picture of the quality of care and service that can then be used for quality and safety management purposes. Audits are only one of the activities within a comprehensive quality management system. Audits ensure compliance; they do not ensure quality.
- In the past, conducting an audit was one response to an adverse event or a complaint, especially those that may have garnered media or public attention. In these situations, however, there are other quality and safety tools that would be far more effective, such as conducting a systems-level safety analysis to fully understand what has occurred, why, and what needs to be improved.

Recommendation 3

The Ministry of Health and AHS improve auditing processes in continuing care including CCHSS, Accommodation Standards, and accreditation with a goal to remove redundancy and improve efficiency. When redesigning the audit processes, some general principles should be considered:

- Consistent application across the province and across the three continuing care streams.
- Auditing to be done by a group that is removed from frontline or zone operations.

- Separation of the auditing process from the process that provides quality improvement support and coaching.

Required actions

- The Ministry of Health and AHS explore combining the Accommodation Standards and CCHSS auditing processes.
- The Ministry of Health and AHS publicly report the results of CCHSS audits.
- The Ministry of Health and AHS ensure that the CCHSS audit tool includes mechanisms to assess the rigour of the provider's quality improvement program to verify that performance measures are used to continuously identify improvement opportunities and that processes are in place for implementing improvement strategies.

Recommendation 4

The Ministry of Health and AHS provide clarity on the role and requirement for accreditation in quality and safety management for continuing care.

Required actions

- The Ministry of Health review, and revise if required, the ministerial directive *Mandatory Accreditation in Alberta's Health System*, to provide clarity regarding the requirement for mandatory accreditation for continuing care contracted service providers.
- AHS develop a plan, with clear timelines, to ensure and monitor the accreditation status of all contracted service providers.

Continuous performance measurement

Issue

The information available from the interRAI assessment tool is being underused for quality monitoring and evaluation at all levels of the continuing care system.

Analysis

By providing a common approach to assessment, care planning, and outcome measurement, interRAI assessments are designed to serve as an integrated health information system linking all sectors in the continuum of care.[61,124,125,126] In addition to supporting the development of care plans for clients, the assessment can be repeated over time to track outcomes of care related to depression[72,73] cognitive function,[74] physical disability,[75] pain,[76] behaviour,[77] pressure ulcer risk,[78] and frailty.[79,80] These instruments can also be used at the individual level to support allocation of resources to match individual needs.

One of the key benefits of the interRAI assessment instruments is that they allow for health information that is gathered once during the initial assessment and in routine care to be used at other times by many others for multiple applications. Therefore, this 'ask once, use many times' approach provides a cost-effective way to serve the information needs of a broad-based quality and safety management system. This information can be used to support quality improvement, funding, service planning, policy development, program evaluation, and applied research aimed at improving the health and well-being of

vulnerable people. The use of interRAI assessment data to calculate quality indicators is extremely useful for performance improvement in continuing care. The most recent generation of quality indicators for nursing homes[68] and home care[65] used in the Canadian Institute for Health Information's (CIHI) reporting system places a greater emphasis on outcome-based measures of improvements and decline in health. The quality indicators also use more sophisticated risk-adjustment techniques to establish a level playing field in quality comparisons.

Alberta began implementation of interRAI's Resident Assessment Instrument (RAI 2.0) and Resident Assessment Instrument for Home Care (RAI-HC) before 2010.[113] It is expected that Alberta will begin submitting data to CIHI's Continuing Care Reporting System (CCRS) in 2014 and Home Care Reporting System (HCRS) in 2015, which will provide the province the first opportunity to participate in national quality benchmarking initiatives for these two sectors.

interRAI instruments are in use to varying degrees across the province; that is, the interRAI LTC is more widely used than the interRAI HC. This means that the reporting and use of the interRAI data, including the interRAI quality indicators, is variable. For example, some zones are only using the interRAI tools for assessment, while others are also using it for care planning. The use of the quality indicators for quality monitoring and improvement is quite limited.

In 2012, as part of the Quality Enhancement in Continuing Care Project – RAI Quality Review Project, it was identified that there was no provincial review mechanism in place to validate the structure, business rules, and outcomes of the interRAI assessment process.[114] This project is currently being implemented across the province.

In order to improve client experience and care outcomes, system-level outcomes will be more readily available when all data, historical and current, from interRAI HC is included in the Alberta Continuing Care Information System (ACCIS). Consistency of indicators, measures, and reporting will be enhanced with the maturing of the interRAI data collection processes and the ACCIS data reporting system. A complete dataset in the ACCIS database will increase opportunities to examine quality measures from a population perspective.

An anticipated future use of interRAI is to integrate this information with financial information to produce cost-effectiveness measures that will support AHS's overall vision of 'Better Quality, Better Outcomes and Better Value'.[127]

There is variability across AHS zones and service provider organizations in the resources available to support analysis and reporting. Some AHS zones and service providers have dedicated quality and safety and data analytics support while other zones and service providers do not.

Providing the public with access to provider-level quality information can help with provincial quality improvement in a variety of ways. First, it provides any interested stakeholder, including members of the general public, a transparent and scientifically sound source of evidence about quality in the province. Second, it provides a common benchmarking framework service providers can use to set their own quality improvement goals. Third, it allows people needing care, and their family members, to make informed choices about the organizations from which they will seek continuing care services.

Recommendation 5

The Ministry of Health and AHS complete the implementation and support the full use of the interRAI assessment instruments and the Alberta Continuing Care Information System (ACCIS).

Required actions

- Make interRAI information available to all continuing care stakeholders for continuous quality and safety management.
- Ensure appropriate, dedicated resources at all levels (micro and macro) to support measurement, analysis, monitoring, and evaluation of interRAI information and the identification and implementation of improvement opportunities.
- Provide the public with access to site/provider-level quality information.

Surveys

Issue

Continuing care lacks a standardized, consistent, and province-wide approach to administering client and family experience surveys.

Analysis

Current approaches to evaluating patients' experience in healthcare settings tend to ask specific questions about how people feel in the setting (e.g., perceived safety, sense of belonging, having meaningful things to do) and about how they feel they are treated by staff (e.g., staff respect privacy, respond in a timely manner). These approaches deal both with quality of life while receiving care and the aspects of quality of care that overlap with quality of life.[51] However, there are limitations to measuring patient experience in that these measures only provide a partial answer to questions related to quality in continuing care settings. The most important constraint is non-response bias.[52] People may be excluded from these surveys because they refuse to participate for a variety of reasons, including concerns about the confidentiality of their responses and potential repercussions if they give negative ratings. In addition, large portions of the continuing care population may be excluded due to cognitive or communication impairments. Feedback from families is equally important but it cannot be assumed to be a proxy for the client. Family and resident experience data are not interchangeable; however, each represents an important aspect of quality feedback.

Continuing care service provider organizations must have a process whereby clients can evaluate or comment on the services provided, including making satisfaction surveys available to clients. This has resulted in a variety of survey questionnaires and processes across the three continuing care service streams and across the many service provider organizations. For example, of the surveys reviewed for one of the streams in one AHS zone, questions are asked of either clients and/or families and similar topic areas are explored but using different questions. This prevents any opportunity to compare between sites or across or between AHS zones or to aggregate data at a provincial level for reporting and quality improvement purposes beyond the individual-site level. Often these questionnaires are developed 'in-house' without any form of reliability or validity testing and are administered using various methodologies (i.e., phone or face-to-face interview, web-based, and paper). The result is that no

two survey processes are alike and therefore the quality of care and services cannot be consistently measured or compared.

The HQCA's survey of residents and families in *long-term care centres* across the province, which began in 2007, was repeated in 2010, and data collection for a third survey was initiated in March of 2014. The results of the surveys are shared with long-term care stakeholders across the province, and each participating site receives site-specific results. The results are shared with residents and families in an aggregated provincial-level report[108] and reported publicly by AHS. When the 2014 survey process is complete, three separate years of comparable data will be available for continuing care stakeholders to compare at a site, zone, and provincial level.

In late 2013, the first provincial survey of residents and families in *supportive living environments* (SL3, SL4 and SL4D) was initiated by the HQCA. These results are scheduled for public release in the fall of 2014. In 2014/15, the HQCA will conduct a pilot study to survey clients receiving *home care services*, followed by a province-wide survey.

The HQCA surveys use a stringent sampling and survey methodology and incorporate rigorous validation, cognitive, and pilot testing to ensure reliability and comparability.

Recommendation 6

The HQCA continue to build on the work completed to date to establish valid, reliable, and consistent province-wide client and family survey tools and processes for long-term care, supportive living, and home care that support and facilitate quality improvement efforts throughout the continuing care system.

Safety reporting

Issue

No single repository exists of continuing care safety information from across the province.

Analysis

At present, there are various mechanisms within AHS for the reporting of safety information in continuing care. These include the mandatory reportable incident process; staff reporting of hazards, hazardous situations (close calls), and patient harm events; reporting from clients or families (in the form of complaints and concerns); and Protection for Persons in Care reports.

The reportable incidents process is mandatory and a requirement of the CCHSS. Specific criteria have been defined for what must be reported by continuing care providers. Completed forms are submitted electronically to the Ministry of Health and AHS simultaneously, but the information is entered into separate databases or spreadsheets.

Systems exist within AHS for staff and physicians to report their safety concerns, including when patients experience harm events or close calls; contracted providers and patients and families, however, are not able to report into it. The service providers have their own individual processes and systems for reporting as required by the CCHSS. Those contracted providers who are under AHS' new contract (master services agreement) are required to report incident information to AHS. Information is reported

by the contracted providers on a monthly or quarterly basis, and includes the number of incidents broken down into some broad categories, such as medication errors and falls.

Patients and families are provided different mechanisms to report safety concerns. They can complain directly to service providers, and these complaints are managed and responded to through the service provider's internal processes. This information is not necessarily shared with the Ministry of Health or AHS, unless it meets the criteria of a reportable incident or if it is reported to the Protection for Persons in Care office. When care is provided directly by AHS, patients and families may complain to the person providing the care or to AHS management, where it may be dealt with directly, or they may launch a formal complaint through AHS' Patient Relations Department. The Ministry or the Minister of Health may also receive a concern and this will either be managed by the Ministry or be given to AHS or the service provider to address. Lastly, complaints about the conduct or competency of an individual healthcare provider can be made directly to the provider's professional regulatory body.

Any individual can also report an allegation of abuse to Protection for Persons in Care. These complaints are reviewed and responded to by the office of Protection for Persons in Care within the Ministry of Health. If the allegation is related to an AHS facility, the Ministry will notify AHS through the office of the chief executive officer. AHS logs and tracks these complaints on a separate spreadsheet.

The use of all of these various mechanisms for reporting means that there is not one single repository of safety information in the province. This significantly limits the ability of the continuing care system to identify, analyze, and trend safety issues, and thus significantly hampers effective quality and safety management.

Safety experts recognize the importance of having a safety reporting system so that safety information is widely shared, and thus the organization can learn and make improvements.

Recommendation 7

AHS develop a plan for incorporating all continuing care safety information (e.g., reportable incidents, hazards/hazardous situations, close calls, patient harm events, concerns, and PPC reports) from AHS staff, physicians, and contracted service providers to effectively identify and analyze safety issues, share safety information across the continuing care system, and inform system improvement.

Roles and responsibilities

Issue

Quality and safety management in continuing care lacks clarity in roles, responsibilities, and accountabilities among the Ministry of Health, AHS, and contracted providers. Within AHS alone there is a similar lack of clarity regarding roles and responsibilities for quality and safety management in continuing care.

Analysis

Responsibility and accountability for the continuing care system can best be described by looking at the roles of the provincial government (including the Ministry of Health), the health authority (AHS), and the contracted service providers. These responsibilities have been articulated in the Continuing Care Health Service Standards (CCHSS)[18] and in the *Coordinated Access to Publicly Funded Continuing Care Health Services: Directional and Operational Policy*.[1] The Government of Alberta establishes the

legislative and regulatory framework in which the health system operates. AHS is responsible for delivering continuing care services and sets operational policy that aligns with the Ministry of Health's directional policy. AHS implements the CCHSS, and monitors, evaluates, and reports on continuing care service performance. AHS may provide continuing care health services directly or may delegate the delivery of services through a contract agreement with a provider. Contracted service providers are responsible for adhering to the contract with AHS, providing continuing care services, and ensuring compliance with the CCHSS and, where applicable, the Accommodation Standards.

Despite these efforts, a lack of clarity still exists in roles, responsibilities, and accountabilities. For example, the CCHSS state that operators (contracted providers) report to AHS as well as the Ministry of Health.[18] This means the contracted service providers may approach the Minister directly even though they have a contractual relationship with AHS. This could result in both the Minister and AHS providing frontline direction.

There is also a lack of role clarity between the Ministry of Health and AHS when it comes to managing patient harm events or situations that attract media attention or involve a public perception of a quality or safety issue. For example, there have been situations in which both the Ministry and AHS conducted CCHSS audits within a day of each other at a continuing care facility where a concern had been raised. This duplication of effort is an inefficient use of resources and, potentially, creates inconsistent direction. Moreover, the continuing care operator may also conduct an internal review of a situation.

Within AHS itself a lack of clarity is evident in terms of roles, responsibilities, and accountabilities. AHS' organizational structure has a combination of provincial and zonal responsibilities. Community, Seniors, Addiction & Mental Health and the Seniors' Clinical Strategic Network both have a role in improving healthcare services for seniors. On the AHS organizational chart, they are distinctly separate from frontline operations and where implementation of policy and best practice occurs at the zone level. In the current organizational structure, these portfolios do not connect until they reach the level of the official administrator.

There was variable understanding of the roles and responsibilities of the AHS provincial departments; some zones identified them as being instrumental in identifying and implementing best practice, while others said they interacted with provincial departments on an as-needed basis only.

The functions of quality and safety management need to be clearly defined to ensure optimal care is provided. Such an accountability matrix is shown in Table 8 for consideration.

Recommendation 8

The Ministry of Health and AHS develop an accountability matrix for continuing care that clearly delineates the lines of responsibility and accountability for quality and safety management from the Ministry to AHS, and from AHS to contracted service providers.

Recommendation 9

AHS ensure clear lines of accountability and responsibility for quality and safety management in continuing care.

Table 8: An example of a quality and safety management accountability matrix

Q&SM Functions ⇒ / Accountabilities ⇓			Measure / Monitor / Evaluate									Identify		Improve	Mitigate risk
			Continuous performance measures	Accreditation	Audits	Safety Reporting: Organization reports	Safety Reporting: Reportable incidents	Safety Reporting: PPC reports	Surveys	Client concerns	Safety event analysis	Opportunities to improve quality	Hazards / hazardous situations		
Healthcare providers			Participate in data collection if asked	Participate if asked		Report possible issues using the appropriate procedures identified by the organization or funder				Inform clients how to register a concern	Participate in interviews if asked	Report possible issues to the organization		Participate if asked in quality improvement/risk mitigation initiatives	
Organization	Contracted provider	Microsystem	Review local data – determine if results are meeting goals	Participate in reviews/audits as requested		Review individual reports and trend reports	• Report possible issues to Ministry of Health • Participate in investigations as requested		Be aware of organization's results and any local results	Review and trend concerns over local care provided	Participate in system analysis as required	Based on data – make decisions about goals for improvement	Review local safety reports/client concerns that identify hazards/hazardous situations	Conduct QI projects Implement successful improvements	Test local strategies to mitigate risk Inform organization of strategies and results
	AHS	Macrosystem	Review data across microsystems and for specific client populations – determine if results are meeting goals	Facilitate external reviews/audits Conduct internal audits of efforts to improve quality/mitigate risk Contract/coordinate accreditation process		Create a procedure for providers and clients to report harm and near harm Produce reports (send to accountable people) Analyze/trend reports			Analyze/trend reports	Create a procedure Review and trend concerns	Conduct a systems analysis	Establish a process to identify and prioritize QI opportunities and risk of harm mitigation strategies Assign accountability for projects	Review all safety reports/client concerns that identify hazards/hazardous situations – establish a procedure for responding to identified issues	Conduct QI projects Implement successful improvements	Test organization strategies to mitigate risk Implement successful strategies
Funder / Contract holder	AHS		Assure process completed	Create requirement for accreditation/audits		Assure valid policies/procedures are in place and being used	Follow up valid reports Issue order to organization(s) for required changes		Contract/coordinate process Review reports	Assure valid policies/procedures are in place & being used Provide a second review process when requested	Assure systems analyses are conducted according to standards	Assure valid policies and procedures are in place and being used Request reports on issues/events that have been identified and plans for improvement/mitigation of risk/analysis of harm events		Assure organization follows a valid QI process	Assure organization follows a valid process to mitigate risk
	Ministry of Health		Review outcome data	Assure organization complies with recommended improvements				Follow up valid reports Issue order to organization(s) for required changes							

PPC – Protection for Persons in Care; Q&SM – Quality and Safety Management

SUPPLEMENTARY FINDING

"High-performing healthcare systems are those that have created effective frameworks and systems for improving care that are applicable in different settings and sustainable over time."[24]

Although not the focus of previous reviews conducted by the HQCA, a theme has emerged regarding the need for a comprehensive quality and safety management framework for Alberta's healthcare system. This was reinforced during the course of this review. A scan of healthcare systems and ministries across Canada indicated that quality management components are used, and are integrated, to varying degrees in continuing care; however, no examples of a comprehensive quality and safety management framework or system could be found.

The literature review identified a wide variety of safety and quality management models, concepts, approaches and tools but did not identify a unifying, comprehensive framework for healthcare. Many of these models exist in non-healthcare industries, with high-level concepts that can be applied to healthcare systems. Typically, manufacturing industries focus on quality management approaches. High-risk and high-reliability industries such as aviation, rail transportation, and nuclear power have developed the concept of safety management systems. Often, quality management and safety management in non-healthcare industries are addressed separately. In healthcare it is rare to find well-defined approaches for managing quality and managing safety systematically across an entire healthcare system.

Also integral to a quality and safety management framework are core functions that 'operationalize' the high-level concepts of a quality and safety management model and make them applicable for the healthcare system.

Measure/monitor/evaluate: improvement starts with some form of measurement or evaluation following the axiom 'you manage what you measure'. Measurement serves to create the evidence for change when results are less than desired, and helps to establish obtainable targets. Measurement also serves to create a baseline to which future system changes can be compared. Donabedian described measuring three characteristics of a system that could be assessed to reflect quality: the *outcomes* of care, the *processes* that are undertaken that produce the outcomes, and the system's *structure* – those elements that are in place to support the processes.[44] An indicator can be defined as a measure used over time to determine the performance of functions, processes, and outcomes. It can be used to assess the adherence to a standard, achievement of quality goals, or as a quantifiable value that can be used to evaluate performance over time, rather than just a 'snapshot' evaluation. Indicator monitoring often provides a valuable addition to standards-based evaluation, since indicators often focus on a few key structures, processes, or outcomes that represent an overall picture of quality of the organization.[45] Appropriate measures at different levels of the health system are required to facilitate improvement.[46]

Identify opportunities for improvement: information from measuring/monitoring/evaluating can be used to identify opportunities to improve the quality of care and to identify safety hazards and hazardous situations. Because of the volume of information and opportunities for continuous improvement that exist in any system, healthcare organizations need to decide how they will use criteria-based decision making to determine which improvement activities will take priority.[27,37] Decisions made with the goal of mitigating the risk of harm to patients are typically based on assessing the probability that a hazard or hazardous situation will lead to harm, the number of patients that could be affected, and the severity of harm that could be expected.

Improve the system: working in teams, employees are empowered to take action on the improvement opportunities using "practical methods and tools".[27,28,29] There are numerous quality improvement methodologies that can be employed to support an effective system redesign. When safety is the focus of improvement efforts, a human factors-based approach is often undertaken to understand error-provoking conditions with a view towards making structural changes to the system that address such conditions. Once improvement ideas have been tested and evaluated, the changes must be implemented.

Throughout Alberta's system, the elements of quality management are employed in varying degrees of implementation and integration. Some health service provider organizations are using performance measurement, safety learning systems, standards compliance and accreditation, and patient experience data to inform quality improvement decision-making. These approaches are not always integrated into an overarching quality and safety management system, however. Perhaps the clearest evidence of the lack of integration is the many information/data systems that exist in silos, creating barriers to shared systemic learning.

The Ministry of Health in Alberta recently conducted an environmental scan on governance structures for quality assurance. The conclusion from the scan was that "despite a focus on health quality improvement and management in recent years, a formalized governance structure for health quality assurance does not exist in Alberta". The purpose of the document is to guide further development in quality management in Alberta.[128] In addition, the Ministry has developed a Health Systems Outcome and Measurement Framework and in the 2014-2017 business plan has identified the following priority initiative: "Develop an Assurance Framework to provide Albertans with assurance of the quality of care and client safety provided in health care facilities".[129]

The Minister's Forum on Continuing Care is intended to serve as a new partnership between the Ministry of Health, Alberta Health Services (AHS), and continuing care providers to discuss and address policy issues with the goal of strengthening the continuing care system today and in the long term.[130] One of the policy directions considered by forum members was public assurance. It was recognized that assurance is the responsibility of the province and that greater alignment is required between the Ministry of Health, AHS, and continuing care providers to achieve this.

Alberta Health Services (AHS) has recently identified the need for a quality management framework for continuing care. It has developed a draft framework and held two workshops with stakeholders that included the Ministry of Health and contracted service providers to provide input into the framework. The resulting framework is proposed to represent a shared understanding of how quality of care will be defined, measured, reported, and continuously improved, including identification and mitigation of risk.[131]

However, despite the work completed to date, the province is still lacking an overarching integrated approach to quality and safety management. The HQCA has identified a plan to develop a quality and safety management framework for the province in its 2014-2015 business plan.[132] Without a consistent and overarching quality and safety management framework, there is a risk that quality and safety resources are used ineffectively, that care staff are overburdened with inefficient monitoring activities, and that the system cannot as readily learn about and adopt practices that improve the quality and safety of continuing care for Albertans.

A provincial quality and safety management framework that standardizes terminology and the application of core principles and functions would ensure a systemic way of thinking and approaching

quality management that would help to embed these important concepts into Alberta's health system now and in the future. The framework should be applicable to the various sectors or areas of need across the health system as defined by the Alberta Quality Matrix for Health: being healthy, getting better, living with illness or disability, and end of life.[133] In fact, as identified above, Alberta would be leading the way in developing and establishing a provincial framework for quality and safety management.

The development of a provincial framework would benefit from the engagement of health system stakeholders from across the province and representing health service sectors, provider and health professional organizations, the Ministry of Health, and academia. In addition, utilizing national and international experts in quality and safety management from healthcare and non-healthcare industries for external validation would ensure all aspects of quality and safety management have been addressed.

APPENDICES

Appendix I: Request letter

ALBERTA
HEALTH

Office of the Minister
MLA, Edmonton-Rutherford

SEP 9 2013

SEP 0 9 2013

Dr. Tony Fields
Chair
Health Quality Council of Alberta
519, 10235 - 101 Street
Edmonton, Alberta
T5J 3G1

Dear Dr. Fields:

Further to our recent discussion, and in accordance with Section 15(1) of the *Health Quality Council of Alberta Act*, I hereby request that the Health Quality Council of Alberta review and report on quality assurance with respect to the provision of home care services.

The review shall examine the adequacy and monitoring of quality assurance processes utilized by Alberta Health Services (AHS) with respect to home care services delivered directly by AHS and by providers under contract to AHS to deliver home care services. This should include, but is not limited to, specific quality standards, monitoring and auditing for compliance, processes to address identified deficiencies and contract management for external providers.

As part of its report, the Council may make any recommendations it determines necessary to improve the quality of home care services provided to Albertans.

Please develop proposed Terms of Reference and forward to the Deputy Minister of Health at your earliest convenience. Your final report should be provided to me no later than February 28, 2014. The report will be made public.

Thank you for your assistance.

Sincerely,

Fred Horne
Minister of Health

cc: Janet Davidson, Official Administrator, Alberta Health Services
Susan Williams, Acting Deputy Minister, Alberta Health
Dr. John Cowell, President and Chief Executive Officer, Health Quality Council of Alberta

208 Legislature Building, 10800 - 97 Avenue, Edmonton, Alberta T5K 2B6 Canada Telephone 780-427-3665 Fax 780-415-0961

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Appendix II: Follow-up letter

ALBERTA
HEALTH

Office of the Minister
MLA, Edmonton-Rutherford

AR 114737

Dr. Tony Fields
Chair
Health Quality Council of Alberta
519, 10235 - 101 Street
Edmonton, Alberta
T5J 3G1

Dear Dr. Fields:

Further to my letter of September 9, 2013, and in accordance with Section 15(1) of the Health Quality Council of Alberta Act, I hereby request that the Health Quality Council of Alberta (the Council) expand its review to include quality assurance with respect to the provision of continuing care services.

As with the review of home care services, the Council shall examine the adequacy and monitoring of quality assurance processes utilized by Alberta Health Services and those providers contracted by Alberta Health Services to deliver continuing care services. It should include but is not limited to specific quality standards, monitoring and auditing for compliance, processes to address identified deficiencies, and contract management for external providers.

As part of its report, the Council may make any recommendations it determines necessary to improve the quality of continuing care services provided to Albertans.

Please develop proposed Terms of Reference for this additional review and forward them to the Deputy Minister of Health at your earliest convenience. Your final report should be provided to me no later than February 28, 2014. The report will be made public.

Sincerely,

Fred Horne

Fred Horne
Minister of Health

cc: Janet Davidson, Deputy Minister
Dr. John Cowell, Official Administrator, Alberta Health Services
Dr. Patricia Pelton, Acting President and Chief Executive Officer, Health Quality Council of Alberta

208 Legislature Building, 10800 - 97 Avenue, Edmonton, Alberta T5K 2B6 Canada Telephone 780-427-3665 Fax 780-415-0961

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Appendix III: Terms of reference

HQCA

Promoting and improving patient safety and health service quality across Alberta

Review of Quality Assurance in Continuing Care Health Services in Alberta

Terms of Reference

Purpose

Pursuant to section 3 (1), 6 (2), and 15 (1) of the *Health Quality Council of Alberta Act*, the Health Quality Council of Alberta (HQCA) will expand its independent review of quality management, including quality assurance, in home care services to include quality management, including quality assurance, of continuing care health services (home care, supportive living, and long-term care) in Alberta.

Objectives

The HQCA will conduct a review that examines the adequacy and monitoring of quality management and quality assurance processes utilized by Alberta Health Services (AHS) with respect to continuing care health services delivered directly by AHS and by providers under contract to AHS to deliver continuing care health services. This includes but is not limited to:

- Specific quality management standards,
- Monitoring and auditing for compliance,
- Processes to address identified deficiencies.

Scope

This review will not include an examination of access to continuing care services, the type or scope of services provided, the funding of continuing care services, the individual providers of continuing care services, the Accommodation Standards (or quality assurance activities related to the Accommodation Standards), or aspects of contract management beyond quality management. The review will be limited to publicly-funded continuing care health services, and will exclude services that are privately funded.

Based on the review findings and analysis the HQCA will make recommendations about the adequacy and monitoring of quality management processes in continuing care with respect to the above.

Stakeholders

Stakeholders that may be engaged in the review process include but are not limited to:

- Alberta Health Services
  - Primary and Community Care portfolio
  - Quality and Healthcare Improvement
  - Contracting, Procurement and Supply Management
  - Relevant staff within the five operational zones
- Government of Alberta - Alberta Health
  - Health Standards Management

[illegible]

    - Monitoring and Investigations Branch
    - Standards Compliance and Licensing Branch
    - Seniors Services and Continuing Care Division
- Relevant associations, such as the Alberta Continuing Care Association
- Accreditation Canada

Deliverables and Timelines

An interim report will be presented to the Minister of Health on February 28, 2014. A full report of the findings and recommendations will be presented to the Minister of Health on April 30, 2014. The final report will be made public.

Approved by the Board of the Health Quality Council of Alberta:

A.L.A. (Tony) Fields CM MD FRCPC FACP
Chair, Health Quality Council of Alberta

December 23, 2014
Date

[illegible]

QUALITY MANAGEMENT
LITERATURE REVIEW

Prepared for

Health Quality Council of Alberta

February 14, 2014

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1.0 Executive Summary

The purpose of this literature review was to identify, from the past twenty years of published and grey literature, an inventory of models of safety management and quality management in healthcare settings and beyond, to provide background information for the potential development of a provincial model of quality management in healthcare settings.

The literature includes a wide variety of safety and quality management models, concepts, approaches and tools, some of which are comprehensive and some of which are specific and targeted. Most of the models are not discrete as they have evolved from shared concepts and methods and overlap in their methodologies and applications. For example, the PDCA cycle can be used as a quality improvement model in its own right but is also incorporated as a component of several models such as the IHI Model for Improvement, Continuous Quality Improvement and others.

Quality and safety management thinking originated over a century ago. It is apparent that the concepts have evolved continuously to meet the presenting quality and safety concerns of the time. In the first half of the twentieth century, technical considerations were top of mind, ensuring the integrity of the manufactured product and preventing mechanical deficiencies. Later in the twentieth century, human considerations became more of a focus, understanding the 'man/machine' interface. In the past twenty years, organizational and system perspectives have been dominant, addressing organizational culture and policies.

In the past decade, attention seems to be turning increasingly to 'people' considerations: empowered, knowledgeable staff, engaged stakeholders, concern for patient experience. The 2009/10 NHS Operating Framework stated that 'the safety of care, the effectiveness of care and the patient experience together make a quality service – not one, not even two, but all three - that limiting quality to 'doing no harm' is unlikely to deliver the type of ongoing quality improvement that is needed'.[1]

This report presents an inventory of quality and safety management models, approaches, concepts and tools along with a brief explanation of each. Results of the literature search are presented in sections 4.0, 5.0, 6.0 and 7.0.

Abbreviations

AE - Adverse Event
AIMS - Advanced Incident Management System
API - Associates in Process Improvement
APS - Accident Prone Situations
ASAP - Aviation Safety Action Program
ASRS - Aviation Safety Reporting System
BPC - Business Process Change
BPM - Business Process Management
BPR - Business Process Reengineering
BSC - Balanced Scorecard
BTS - Break Through Series
CQI - Continuous Quality Improvement
CMBA - Congruence Management Business Architecture
CRM - Crew Resource Management
CTQ - Critical To Quality Six Sigma
CUSP - Comprehensive Unit Based Safety Program
DFSS - Design for Six Sigma
DMAIC - Define, Measure, Analyze, Improve, Control
DQC - Deep Quality Concept
EBD - Experience Based Design
EDIT - Error type, direct threat, indirect threat
EFQM - European Foundation for Quality Management
EHR - Electronic Health Record
ELS - Error Likely Situations
ERP- Enterprise Resource Planning
EWR - Executive WalkRounds
FTA - Fault Tree Analysis
FMEA - Failure Mode Effects Analysis
FMAQ - Flight Management Attitudes Questionnaire
HACCP - Hazard Analysis Critical Control Points
HCWP - High Commitment Work Practices
HEMEA - Human Error Modes and Effects Analysis
HF - Human Factors
HFACS - Human Factors Analysis and Classification System
HPWP - High Performance Work Practices
HQM - Human Quality Management
HRM - Human Resource Management
HRO - High Reliability Organization
HRT – High Reliability Teams
ICAO - International Civil Aviation Organization
IDEA - Identify problem; Determine root cause; Evaluate prospective interventions; Act
IOM - Institute of Medicine of the National Academies
IHI - Institute of Healthcare Improvement
JUSE - Japanese Union of Scientists and Engineers
Lean-HC - Lean Healthcare
LFA - Logical Framework Analysis
LMI - Lean Management Initiatives
LOSA - Line Operations Safety Audit
LSS - Lean Six Sigma
MFI - Model for Improvement
P4P - Pay for Performance
PDPCQ - Physician Directed Priority Class Queuing
PEx - Process Excellence
PDCA - Plan Do Check Act
PDSA - Plan Do Study Act
PHReTT - Patient Focused High Reliability Team Training
PI - Process Improvement
PSWR - Patient Safety Walkrounds
QBD - Quality benchmarking deployment
QC – Quality control
QI – Quality Improvement
QMS - Quality Management System
QRA - Quantitative Risk Assessment
RCA - Root Cause Analysis
RPN - Risk Priority Number
SAGAT - Situational Awareness Global Assessment Technique
SAQ - Safety Attitudes Questionnaire
SMS - Safety Management System
SSI - Six Sigma Initiatives
SQC - Statistical Quality Control
SQM - Strategic Quality Management
TeamSTEPPS - Strategies and Tools to Enhance Performance and Patient Safety
TPS - Toyota Production System
TQC - Total Quality Control
TQM - Total Quality Management
TRIZ - Theory of Inventive Problem Solving
VOC - Voice of Customer
VOP - Voice of Provider
VS - Value stream

Definitions

5-S: Sort, Simplify, Sweep, Standardize, Self-Discipline: a visually-oriented system for organizing the workplace to minimize the waste of time.

Adverse Event: An unexpected, unanticipated outcome directly associated with the care provide that results in harm

Aim: A written, measurable, and time-sensitive statement of the expected results of an improvement process.

Benchmarking: A process of searching out and studying the best practices that produce superior performance. Benchmarks may be established within the same organization (internal benchmarking), outside of the organization with another organization that produces the same service or product (external benchmarking), or with reference to a similar function or process in another industry (functional benchmarking).

Best Practices: The most up-to-date patient care interventions, scientifically proven to result in the best patient outcomes and minimize patients' risk of death or complications.

Clinical Pathway: A patient care management tool that organizes, sequences, and times the major interventions of nursing staff, physicians, and other departments for a particular case type.

Close Call: an event or circumstance which has the potential to cause an adverse event but did not actualize due to chance, corrective action and/or timely intervention.

Continuous Quality Improvement (CQI): The ongoing monitoring, evaluation, and improvement of processes; a patient/client-driven philosophy and process that focuses on preventing problems and maximizing quality of care.

Crew Resource Management (CRM): A communication methodology derived from the aviation industry that is based on team-centered decision making systems.

Cycle time: The time required for completing one step of a process.

Failure Modes and Effects Analysis (FMEA): A systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change.

Flow: The progressive achievement of tasks along the value stream so that a product proceeds from design to launch, order to delivery, and raw materials into the hands of the customer with no stoppages, scrap, or backflows.

Global Trigger Tool for Measuring Adverse Events: This tool includes a list of known adverse event triggers and instructions for measuring the number and degree of harmful events. The tool provides instructions and forms for collecting the data needed to measure Adverse Events per 1,000 Patient Days and Percent of Admissions with an Adverse Event.

Harm: An unexpected (unanticipated) or normally avoidable outcome that negatively affects a patient's health, quality of life and occurs or has occurred during the course of receiving health care services.

Hazard: A set of circumstances or a situation that could harm a person's interests such as their health or welfare.

Health Outcomes: The effect on health status from performance (or non-performance) of one or more processes or activities carried out by healthcare providers. Health outcomes include morbidity and mortality; physical, social, and mental functioning; nutritional status; etc.

Human Error: The failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given gain.

Human Factors: The application of information about human behavior, abilities, capacities and limitations to the design of tools, systems, tasks and environments that result in safe, productive, comfortable and effective human use.

Health Care Intervention: Any type of treatment, preventive care, or test that a person could take or undergo to improve health or to help with a particular problem. Health care interventions include drugs (either prescription drugs or drugs that can be bought without a prescription), foods, supplements (such as vitamins), vaccinations, screening tests (to rule out a certain disease), exercises (to improve fitness), hospital treatment, and certain kinds of care (such as physical therapy).

Implementation: Taking a change and making it a permanent part of the system. A change may be tested first and then implemented throughout the organization.

Incident Reporting: Refers to the identification of occurrences that could have led, or did lead, to an undesirable outcome. Reports usually come from personnel directly involved in the incident or events leading up to it (e.g., the nurse, pharmacist, or physician caring for a patient when a medication error occurred).

Indicator: A measurable variable (or characteristic) that can be used to determine the degree of adherence to a standard or the level of quality achieved.

Institute of Healthcare Improvement (IHI): A not-for-profit organization driving the improvement of health by advancing the quality and value of healthcare. The Institute helps accelerate change in healthcare by cultivating promising concepts for improving patient care and turning those ideas into action.

Institute of Medicine (IOM): An organization within the National Academy of Sciences that acts as an advisor in health and medicine and conducts policy studies relevant to health issues. The IOM was chartered in 1970 by National Academy of Science to enlist distinguished members of appropriate professions in the examination of policy matters pertaining to the health of the public. The IOM is an advisor to federal government on issues of medical care, research, and education.

Just Culture: A healthcare approach in which the provision of safe care is a core value of the organization. Opportunities to proactively improve the safety of care are constantly identified and acted on. Providers and patients are appropriately and adequately supported in the pursuit of safe care. The culture encourages learning from adverse events and close calls to strengthen the system, and where appropriate, supports and educates health care providers and patients to help prevent similar events in the future. There is a shared commitment across the organization to implement improvements and to share the lessons learned. Justice is an important element. All are aware of what is expected, and when analyzing adverse events any professional accountability of health care providers is determined fairly. The interests of both patients and providers are protected

Kaizen: Continuous, incremental improvement of an activity to create more value with less *muda*.

Key Changes: The list of essential process changes that will help lead to breakthrough improvement.

Lean Production: A business system for organizing and managing product development, operations, suppliers, and customer relations that requires less human effort, less space, less capital, and less time to make products with fewer defects to precise customer desires, compared with the previous system of mass production. Lean production was pioneered by Toyota after World War II.

Measure: An indicator of change; a measure is used to track the delivery of proven interventions to patients and to monitor progress over time.

Measurement: The process of collecting data to assess performance conducted at a single point in time or repeated over time.

Model for Improvement: An approach to process improvement, developed by Associates in Process Improvement, which helps teams accelerate the adoption of proven and effective changes.

Muda: Waste.

Outcomes: Benefits or other results (positive or negative) for clients that may occur during or after their participation in a program. Outcomes can be client-level or system-level.

Outcome Measure: A measure that indicates the result of the performance (or non-performance) of a function or process

Patients: People who directly or indirectly make us of health services.

Patient-Centeredness: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring the patient's values guide all clinical decisions.

Patient Safety: The reduction and mitigation of unsafe acts within the healthcare system as well as through the use of best practices shown to lead to optimal patient outcomes.

Patient Safety Leadership WalkRounds: An informal method for leaders to talk with front-line staff about safety issues in the organization and show their support for staff reported errors.

Patient Satisfaction: A measurement that obtains reports or ratings from patients about services received from an organization, hospital, physician, or healthcare provider.

Patient Values: The unique preferences, concerns, and expectations that each patient brings to a clinical encounter that must be integrated into clinical decisions if they are to serve the patient.

Patient-Centred Care: Care that is respectful of and responsive to individual patient preferences, needs, and values and ensures patient values guide all clinical decisions, care that is coordinated, communicative, and supportive.

Pay for Performance: A direct financial reward model or quality bonus; incentive and reward models where there are direct provider dollars at stake for quality improvement.

Performance: the way in which an individual, a group, or an organization carries out or accomplishes its important functions and processes.

Performance Measure: A quantitative tool that provides an indication of an organization's performance in relation to a specified process or outcome.

Pilot Site: The clinic location for initial focused changes. After implementation and refinement, the process will be spread to additional locations.

Plan-Do-Study-Act (PDSA): A widely used framework for testing change on a small scale.

Process: A sequence of tasks to get to an outcome; a goal directed interrelated series of actions, events, mechanisms, or steps.

Process Measure: A series of actions, functions, or changes, which lead to a certain anticipated outcome. A scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome.

Process of Care: A healthcare service provided to, on behalf of, or by a patient appropriately based on scientific evidence of efficacy or effectiveness.

Protocol: A detailed plan, or set of steps, to be followed in a study, an investigation, or an intervention, as in the management of a specific clinical condition.

Pull: A system of cascading production and delivery instructions from downstream to upstream activities in which nothing is produced by the upstream supplier until the downstream customer signals a need; the opposite of push.

Quality: The degree to which a health or social service meets or exceeds established professional standards and user expectations. Evaluation of the quality of care should consider 1) the quality of the inputs, 2) the quality of the service delivery process and 3) the quality of outcomes, in order to continuously improve systems of care for individuals and populations.

Quality Assessment: Determination of how processes and services correspond to current standards, as well as a patient's satisfaction with the care received.

Quality Assurance (QA): That set of activities that are carried out to set standards and to monitor and improve performance so the care provided will satisfy stated or implied needs.

Quality Improvement (QI): Activities aimed at improving performance; an approach to the continuous study and improvement of the processes of providing services to meet the needs of the individual and others. This term generally refers to the overriding concepts of continuous quality improvement and total quality management.

Quality Indicator: An agreed-upon process or outcome measure that is used to determine the level of quality achieved; a measurable variable (or characteristic) that can be used to determine the degree of adherence to a standard or achievement of quality goals.

Quality Management: An ongoing effort to provide services that meet or exceed customer expectations through a structured, systematic process for creating organizational participation in planning and implementing quality improvements.

Quality Measure: A quality measure, also referred to as a quality indicator, is a formula that converts medical information from patient records into a rate, or percentage, that shows how well a hospital cares for its patients.

Quality Monitoring: The collection and analysis of data for selected indicators that enable managers to determine whether key standards are being achieved as planned and are having the expected effect on the target population.

Quality of Care: The degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Reliability: A failure-free operation over time. Reliability in health care is defined as patients getting the intended tests, medications, information, and procedures at the appropriate time and in accordance with their values and preferences.

Reporting: The communication of information about an adverse event or close call by healthcare providers through appropriate channels inside or outside of healthcare organizations for the purpose of reducing the risk of adverse events in the future.

Risk: A way of expressing the chance that something will happen. It is a measure of the association between exposure to something and what happens (the outcome). Risk is the same as probability, but it usually is used to describe the probability of an adverse event.

Root Cause Analysis: Process of developing permanent solutions to problems by first identifying all of the contributing and underlying causes of a problem.

Safety Culture: Also known as culture of safety, these terms refer to a commitment to safety that permeates all levels of an organization, from frontline personnel to top management.

Sentinel Event: An adverse event in which death or serious harm to a patient has occurred, usually refers to unexpected or unacceptable events, such as operation on the wrong patient or body part.

Six Sigma: A methodology that provides organizations with the tools to improve the capability of their business processes. This increase in performance and decrease in process variation lead to defect reduction and improvement in profits, employee morale and quality of product.

Spread: The intentional and methodical expansion of the number and type of people, units, or organizations using the improvements. The theory and application comes from the literature on Diffusion of Innovation (Everett Rogers, 1995).

System: a group of related processes.

Team: a small number of people with complementary skills who are committed to a common purpose, performance goals, and approach for which they hold themselves mutually accountable. This group of individuals, usually from multiple disciplines, drives and participates in the improvement process.

Test: A small-scale trial of a new approach or a new process. A test is designed to learn if the change results in improvement and to fine-tune the change to fit the organization and patients. Tests are carried out using one or more PDSA cycles.

Total Quality Management (TQM): continuous quality improvement activities and the management of systems that foster such activities: communication, education, and commitment of resources.

Toyota Production System (TPS): The production system developed by Toyota Motor Corporation to provide the best quality, lowest cost, and shortest lead time through the elimination of waste.

Value: A capability provided to the customer at the right time at an appropriate price, as defined in each case by the customer.

Value stream: The specific activities required to design, order, and provide a specific product (or service) — from concept launch to order to delivery into the hands of the customer.

Value stream mapping: Identification of all the specific activities occurring along a value stream for a product or product family (or service)

Variation: A measure of the change in data, a variable, or a function.

Waste: Anything that does not add value to the final product or service, in the eyes of the customer; an activity the customer wouldn't want to pay for if they knew it was happening.

2.0 Introduction

2.1 Purpose of Literature Review

A comprehensive review was conducted of published research literature and grey literature on the models of safety management and quality management in health care settings and in industries beyond healthcare. The purpose of the literature review was to provide background information to the HQCA for the potential development of a provincial model of quality management in healthcare settings.

2.2 Evolution of Quality and Safety Initiatives

Over the past century, the increasing importance and scope of quality issues has led to the inception and development of quality management. Initially, quality management addressed technical control in basic production processes and, over time, this led to total quality management regarding entire enterprises.[2] Each era has had its distinctive contribution to quality improvement. Over many years, based on the work of a number of 'quality gurus', quality management has taken on an increasingly holistic approach equipped with scientific tools. [3]

The concept of quality has evolved to mean far more than the integrity of a manufactured product. Quality now represents a philosophy, a system of methodologies and practices, and an ongoing commitment to business excellence that encompasses all issues and engages all individuals within an organization.[4]

The evolution of quality and safety initiatives is illustrated in developments in the aviation industry. The history safety and quality management in aviation safety can be divided into three eras.[5]

- *The technical era — from the early 1900s until the late 1960s.* Initially, safety deficiencies were identified as related primarily to technical factors and technological failures. Therefore, safety endeavours focussed on the investigation and improvement of technical factors. With the technological improvements in place by the 1950's and a gradual decline in the frequency of accidents, safety processes were broadened to encompass regulatory compliance and oversight.
- *The human factors era — from the early 1970s until the mid-1990s.* In the early 1970s, the frequency of aviation accidents was significantly reduced due to major technological advances and enhancements to safety regulations. With aviation becoming a safer mode of transportation, the focus of safety endeavours was extended to include human factors issues including the man/machine interface. This led to a search for safety information beyond that which was generated by the earlier accident investigation process. Despite the investment of resources in error mitigation, human performance continued to be cited as a recurring factor in accidents. The application of human factors science tended to focus on the individual, without fully considering the operational and organizational context. In the early 1990s, it was acknowledged that individuals operate in a complex environment, which includes multiple factors having the potential to affect behaviour.
- *The organizational era — from the mid-1990s to the present day.* During the organizational era, safety began to be viewed from a systemic perspective, encompassing organizational factors in addition to human and technical factors. The notion of the organizational accident was introduced, and the impact of organizational culture and policies on the effectiveness of safety risk controls was recognized. Additionally, traditional data collection and analysis efforts, which had been limited to the use of data collected through investigation of accidents and serious incidents, were supplemented with a new proactive approach to safety. A safety management approach was enhanced by routine collection and analysis of data using proactive as well as reactive methodologies to monitor known safety risks and detect emerging safety issues.

In recent years, the concept of quality appears to be moving into a new phase. Having commenced as an object-oriented measurement and control activity focusing on the quality of the output of a product or service, with the introduction of Total Quality Management (TQM), it has expanded and reoriented to address the overall management of the organization. In what is called the 'third generation', transparency, accountability and social responsibility are being introduced into the body of knowledge regarding quality management. This concept asserts that, in future, organizations will need to engage increasingly with the broader society in which they operate. The notion of 'trans-activity' underpins the connections between the organization and its societal and business context. The changing concept of quality management will be linked with the increasingly significant notion of stakeholders. A transformed concept of quality management is emerging in which society plays a quintessential part.[6]

While quality management in the past has focused on technical and systems considerations, the attention seems to be turning to 'people' considerations. An engaged, empowered staff[7,8,9] having access to the necessary knowledge[10,11] are being shown to be essential aspects of quality healthcare.

The recent experience in England of the Mid Staffordshire Foundation Trust Public Inquiry provides important lessons regarding the current and future focus of quality management. In his report, Robert Francis, QC, pointed out that the failure of the system showed that a fundamental culture change was needed and that patients must be the first and foremost consideration of the system.[12] While most safety and quality management systems developed over the past century have claimed to have the customer as their focal point, it is argued that, despite the longevity of the 'patient involvement' concept, healthcare systems are still not putting patients first.[13]

2.3 Defining Quality and Its Major Influencing Factors

In 1980, Donabedian defined quality of care as 'the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts'. In the 1990s, the Institute of Medicine defined quality of care as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'. The UK Department of Health stated that quality of care is: 'doing the right things (what), to the right people (to whom), at the right time (when) and doing things right the first time'. The Council of Europe stated that 'quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge'. The World Health Organization, in 2000, stated that 'quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population'.[14]

The literature provides definitions for quality initiatives including:[1]

- *Quality assessment* is about identifying areas for improvement, such as examining clinical audit data, complaints or nursing care indicators to detect failures in quality
- *Quality improvement* is about resolution and setting continuous quality improvement goals., such as quality improvement actions could involve scrutiny of service redesign using 'Lean thinking' or the development of the productive ward
- *Quality assurance* brings quality assessment and quality improvement together, with the aim of building accountability and confidence, and may involve receiving reports and feedback at board or committee level about the processes in place to assess quality and oversee quality improvement actions.

The term 'quality assurance system' refers to organizations and processes for defining, assuring, maintaining and improving quality of care, and the extent to which they provide assurance that essential standards of quality are being met. Principles that should guide the design of the quality assurance system are that it should be patient

centred, engage staff, promote good governance and effective leadership and ensure that all those who are part of the system are clear about their roles.[15]

The Institute for Health Care Research and Improvement stated that health care quality is influenced by the following six factors:[16]

- *Safety*—patients should not be harmed by the care that is intended to help them
- *Timeliness*—unnecessary waits and harmful delays should be reduced
- *Effectiveness*—care should be based on a sound scientific knowledge base
- *Efficient*—care should not be wasteful
- *Equitable*—the quality of care should not vary even though patient characteristics may vary
- *Patient*—care should be responsive to individual preferences, needs, and values (patient centered).

The 2009/10 NHS Operating Framework stated that the safety of care, the effectiveness of care and the patient experience together make a quality service – 'not one, not even two, but all three' – that limiting quality to 'doing no harm' is unlikely to deliver the type of ongoing quality improvement that is needed.[1]

2.4 Quality and Safety 'Gurus'

The literature references many leaders in development of quality concepts and thinking. Some of these are:

Frederick W. Taylor

In 1911, Frederick W. Taylor published 'The Principles of Scientific Management', using statistical theory to provide a framework for improving worker productivity in industrial organizations. Taylor introduced several important concepts, including:

- Functional specialization: defining and allocating tasks to be performed under standard conditions (with inspection as just one of the tasks)
- Process analysis of time and motion to increase productivity.
- Quality control (by inspection of the final product) formalized as a distinct function conducted by individuals *not directly involved* in the production process.

Taylor's contributions are recognized as precursors to several engineering tools and cycle time reduction methods still in use today.[4]

Kaoru Ishikawa

Kaoru Ishikawa was known as the pioneer in the quality revolution in Japan. He advocated for a participatory and bottom-up approach in quality management and is known for his trademark Cause and Effect diagram (fishbone diagram) and Quality Circles.[17]

Walter Shewhart

In the mid-1920s, when he was a statistician at Bell Laboratories, Walter Shewhart began to focus on processes, as opposed to end products alone. In this analysis, he recognized that each individual process yields data, which can in turn be analyzed using statistical techniques to evaluate stability and constancy. This work led to the first systematic approach to quality control (QC) (statistical QC), creating the QC chart, statistical process control and quality improvement.[18] He demonstrated that eliminating variation in the process leads to a good standard of end products.[4]

W. Shewhart's 'Shewhart cycle' consisted of 3 steps:[19]

Step 1 - Specification
Step 2 - Production

Step 3 - Inspection

W. Edwards Deming

Deming's 'Deming Wheel' (1950) consisted of 4 steps:[19]

- Design the product (with appropriate tests)
- Make it; test it in the production line and in the laboratory
- Sell the product
- Test the product in service, through market research. Find out what users think about it and why the nonusers have not bought

Deming popularized the Plan-Do-Check-Act (PDCA) cycle as a methodology for pretesting and perfecting before implementation and for continual improvement.[4] Deming stressed the importance of management's role in the delivery of quality and outlined 14 obligations of management:[20]

- Create constancy of purpose toward improvement
- Adopt the new philosophy
- Cease dependence on mass inspection. Require instead statistical evidence that quality it built into the product
- End the practice of awarding business on basis of a price tag
- Improve constantly and forever the system of production and service
- Institute modern methods of training on the job
- Institute leadership
- Drive out fear
- Break down barriers between departments
- Eliminate numerical goals, poster and slogans asking for new level so productivity without providing methods
- Eliminate work standards (quotas)
- Remove barriers that stand between the hourly worker and his right to pride of workmanship
- Institute a vigorous program of education, retraining and self-improvement
- Create a structure in top management that will push every day on the above 13 points

W. Edwards Deming, working with Joseph Juran, led to the creation of the "total quality approach," which created higher quality exports at lower costs.[18]

Joseph Juran

J. M. Juran defined quality as 'fitness for purpose' and is known for his concepts regarding the cost of quality. Juran proposed the idea of dividing the costs of quality into avoidable costs and unavoidable costs. The 'Juran Trilogy' consisted of three managerial processes: Quality Planning, Quality Control & Quality Improvement.[3]

Juran described quality from a customer point of view, where the degree of quality is proportional to the number of features that meet customers' needs in design, availability, safety, conformance and use. He believed that each person along the chain, from internal customers to the final user is both a supplier and a customer.[4]

Juran identified 8 milestones as integral to a quality planning roadmap:[4]

- Determine who are the customers
- Determine the needs of those customers
- Develop a product that responds to those needs
- Optimize the product features to meet your needs as well as customer needs

- Develop a process that is able to produce the product
- Optimize the process
- Prove that the process can produce the product under operating conditions
- Transfer the process to operations

Avedis Donabedian

Donabedian is often considered the father of quality measurement.[21] He proposed that quality of health care could be measured by evaluating its structure, processes and outcomes as adapted from the concept of input–process–output in industrial manufacturing. He argued that 'good structure increases the likelihood of good process, and good process increases the likelihood of good outcome'.[14]

Donabedian defined the parts as follows:[14]

- Structure (or input): the attributes of the settings in which care occurs and the resources needed for health care; includes material resources (facilities, capital, equipment, drugs, etc.), intellectual resources (medical knowledge, information systems) and human resources (health care professionals).
- Process: the use of resources in terms of what is done in giving and receiving care; can be classified into patient-related processes (intervention rates, referral rates, etc.) and organizational aspects (supply with drugs, management of waiting lists, payment of health care staff, collection of funds, etc.).
- Outcomes: the effects of health care on the health status of patients and populations and comprise final outcomes such as mortality, morbidity, disability or quality of life, as well as intermediate outcomes, for instance, blood pressure, body weight, personal well-being, functional ability, coping ability, improved knowledge and others.

Mitchell Feigenbaum

M. Feigenbaum proposed that high quality products are more likely to be produced through total quality control (TQC) than when manufacturing works in isolation. The underlying principle of this total quality view is that, to provide genuine effectiveness, control must start with the design of the product and end only when the product has been placed in the hands of a customer who remains satisfied.[18]

Feigenbaum contributed to the conceptual foundation and practical application of quality management and is considered the father of Total Quality Management (TQM).[4]

Philip Crosby

Philip Crosby was an executive responsible for quality at International Telephone and Telegraph who theorized that quality is free and that doing the job right the first time is always cheaper (zero defect). His emphasis was on behavioral, organizational and management processes instead of the statistical approach to effect quality change.[17]

Philip Crosby defined quality as 'conformance to specifications' or 'conformance to requirements'.[3,22] He is best known for his advocacy of zero-defects management and prevention as opposed to statistically acceptable levels of quality, his 14 steps to quality improvement and quality management maturity grid. In his maturity grid, he advocated that organizations go through five successive stages of quality maturity as they approach the maximum level of quality in all phases of organizational activity: uncertainty, awakening, enlightenment, wisdom and certainty.[22]

Crosby based his quality improvement process on 'four absolutes of quality'.[4]

- Quality is the conformance to requirements.
- The system of quality is prevention.

- The performance standard is zero-defect.
- The measurement of quality is the price of non-conformance.

James Reason

Reason's Organizational Accident Causation Model developed in the 1990s was originally intended for use in complex industrial systems as a mechanism for understanding the relationships between the theoretical components of organizational accidents, thus helping to identify effective methods of accident prevention. His human factors model has shown to have application to medical accidents and incidents.[23]

Reason's best known work may have been his model for the dynamics of accident causation, sometimes referred to as the 'Swiss cheese' model. Reason's model of accident causation begins with latent failures, and the Swiss cheese plates represent psychological precursors and unsafe acts, local triggers, and failures of other defenses. The trajectory of error opportunity results from the alignment of the holes in the slices of Swiss cheese.[24]

3.0 Project Methods

3.1 Search Methodology

Comprehensive search strategies were developed by an information specialist (TD) using a combination of subject headings and keywords and adapted for 6 electronic bibliographic databases. Searches were conducted in the following electronic databases: Ovid MEDLINE 1946 to December 31, 2013, Ovid MEDLINE In-Process & Other Non-Indexed Citations, and Ovid MEDLINE Daily, EMBASE (Ovid, 1980 to 2013 December 31), Health Business Elite (EBSCOhost, 1922 to December 2013), Compendex (Engineering Index, 1884-current), ABI Inform Global (Proquest, 1970 to present), and Emerald Insight (Emerald, 1898-current).

For the search strategies, a combination of subject headings and keywords were developed for each electronic resource including the following terms: quality management; quality assurance; quality of health care; outcome and process assessment (healthcare); safety management; patient safety management; risk assessment; hazard identification; hazard analysis; risk identification; medical errors; risk management; models, organizational; models; frameworks; continuity of patient care; quality of health care; Plan, Do, Check, Act (PDCA); Total Quality Management (TQM); Continuous Quality Improvement (CQI); LEAN; SIX Sigma; Kaizen; Balanced Scorecard; Integrated Quality Management; European Foundation for Quality Management (EFQM) Excellence Model®; Object Oriented Quality Management (OQM), Management By Walking About (MBWA), McKinsey 7-S Framework, ISO 9000, Joseph Juran; W. Edwards Deming, Armand Feigenbum; Kaoru Ishikawa; Genichi Taguchi; Shigeo Shingo; Philip Crosby; Tom Peters; and James Reason.

The search was limited to English and covered 1993 to December 31, 2013. The search was not limited by study design or publication status.

In consultation with the client, the HQCA, a focused grey literature search of associations, societies, and websites was conducted for quality management and safety management models and frameworks.

References were managed using Reference Manager, Version 11 bibliographic software (Thomson ISI ResearchSoft, Carlsbad, CA).

3.2 Study Selection

A two-step process for article screening was used. First, one reviewer (TD) screened the titles and abstracts (when available) to determine if an article met the general inclusion criteria. General inclusion criteria were a mention of a model or framework for either quality management or safety management. Each article that was determined to be either unclear or included by TD was then further screened by a second reviewer (JA). Full texts of articles that were screened as included or unclear by JA were retrieved for formal review.

Electronic search strategies are presented in Appendix 1.

An article flow chart is presented in Appendix 2.

4.0 Quality Management Models

4.1 Standards Based Models

4.1.1 International Organization for Standardization (ISO)

Since 1947, the International Organization for Standardization (ISO) has developed management and leadership standards for business, government and community, ranging from environmental management to business applications of risk and quality management. The ISO 9000 series, standards that focus specifically on quality management and quality assurance, were developed to help companies achieve customer satisfaction, continuous improvement and regulatory requirements, as well as effectively document the elements needed to maintain an efficient quality system. The series now includes ISO 9000:2005 (definitions), ISO 9001:2008 (requirements) and ISO 9004:2009 (continuous improvement), and is based on eight quality management principles that can be applied by management for organizational improvement:[4]

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision-making
- Mutually beneficial supplier relationships

After a major update in 2000, the new standards are built around business processes, emphasizing improvement and meeting the needs of customers. Adaptable to all types of organizations, ISO 9001 is unique in that it not only specifies the requirements for a Quality Management System (QMS) but also provides tools and a philosophical basis. The benefits of an ISO 9001-based QMS include:[4]

- Documenting processes forces an organization to focus on how they do business
- Documented processes create repetition, eliminate variation, improve efficiency and reduce costs
- Corrective and preventative measures are developed and become permanent company-wide solutions
- Employee morale is increased as they're empowered to take control of their work
- Customer satisfaction/loyalty grows as the company delivers proactive rather than reactive solutions
- Better products and services arise from continuous improvement process
- Improved profit levels as productivity improves and rework costs are reduced
- Improved internal/external communications– employees, customers and suppliers are assured a voice
- Verification by 3rd party auditor builds credibility with customer, supplier and competitive organizations

The ISO standards are generic so the same standards can be applied to any organization, large or small, whatever its product or service, in any sector or activity whether it is a business enterprise, a public administration of a government department. The concept underlying ISO 9000 standards is that the assurance of consistent product or service quality is best achieved by simultaneous application of product standards and quality management system standards. The standards represent an international consensus on good management practices with the aim of ensuring that the organization can continuously deliver the product or service that:[25]

- Meet the customer's quality requirements
- Meet applicable regulatory requirements
- Enhance customer satisfaction
- Achieve continuous improvement of its performance in pursuit of these objectives.

The effect of the ISO-9000 series of quality standards was the harmonization of quality standards that had been developed all over the world. A TQM approach to a production/service system proposed that only a good quality production/service system can produce good quality products or offer good quality services. ISO-9000 involves twenty core requirements for determining a good quality system and has been extensively adopted in manufacturing industries all over the world, particularly for supplier's certification. ISO-9000 certification has also been adopted by many service oriented companies for receiving recognition a "high quality" service companies. [26]

ISO 9000 promotes companies to implement TQM-centered principles such as customer focus.[18] To produce ISO 9000 impacts, the principles should be widely applied and internalized in all aspects of the business, including suppliers and customers. ISO 9000 focuses on only key processes and systems that influence quality and operational performance.[27]

Very few hospitals or health care providers are currently ISO-9000 certified or have sought such certification.[26] ISO takes a systems and process approach to improve organizational and financial performance with a specific focus on quality management, process control and quality assurance techniques to achieve planned outcomes and prevent unsatisfactory performance or non-conformance. World-wide application of ISO 9000 in hospitals has been reported but up to now only on a limited scale.[25]

Hospitals which have used ISO have reported to have successfully implemented a quality management system according to the ISO 9001:2000 standard and to have obtained a certificate of conformance for their hospital organization. Experiences with ISO were reported to be very positive and to have provided a number of advantages. The focus on patients was re-established; all processes had been identified and were subject to continuous improvement. Performance measurements were introduced that gave an overall and integrated picture of results and subsequently led to improvement of quality of care and to improvement of the quality management system.[25]

On the downside, ISO 9001-based quality management systems have been criticized for the amount of money, time and paperwork required for registration and maintenance. Further, ISO 9001 certification does not guarantee product or service quality, especially in cases where receiving certification is prioritized over achieving quality.[4]

4.2 Quality Control (QC) Models

4.2.1 Total Quality Control (TQC)

Feigenbaum first recognized the importance of a comprehensive approach to quality and coined the term Total Quality Control (TQC). Feigenbaum emphasized that the quality of a product or service is directly influenced by what he termed the 9Ms: markets, money, management, men and women, motivation, materials, machines and mechanization, modern information technology, and mounting product/service requirements.[26]

4.2.2 Statistical Quality Control (SQC)

Statistical Quality Control (SQC) was first introduced by Walter Shewhart and Harold Dodge in the U.S. in the early 1950s. Deming introduced the SQC techniques using SQC charts to the manufacturing industry in early 1960s as the most effective and efficient way to control manufacturing quality.[26]

Shewhart saw the measure of quality as a quantity that may take on different numerical values. The measure of quality, no matter what the definition of quality may be, is a variable. For example, quality of an object can be expressed numerically in terms of three variables: height, width, and symmetry. Shewhart's emphasis on measurement in his definition of quality relates to his prescriptions for statistical quality control (SQC), which requires numbers.[3]

SQC has been extensively used in the manufacturing industry for effectively and efficiently controlling quality of manufactured products. SQC has also been used successfully for controlling quality in a number of service industries such as fast food industry, restaurant industry, banking and telephone industries. There is little evidence of successful use of SQC in the health care industry.[26]

4.2.3 Zero Defect Program

The Zero Defect Program, created by NEC Corporation of Japan in the 1960s, was based upon statistical process control and was one of the inputs for the inventors of Six Sigma. (136)=4 The program focused on worker motivation and awareness, with the goal to "promote a constant, conscious desire to do a job right the first time". The zero defects program was said to be heavy on philosophy, motivation, and awareness, and Lean on specific proposals and problem-solving techniques.[3]

4.3 Excellence Models

4.3.1 Malcolm Baldrige National Quality Award (MBNQA)

In 1987, the US Congress established the Malcolm Baldrige National Quality Award to promote competitiveness, performance, and quality leadership in American businesses.[17]

Baldrige Health Care Criteria for Performance Excellence Framework are:[26]

- Leadership
- Strategic planning
- Customer and market focus
- Information and analysis
- Human resource focus
- Process management
- Business results

The 7th criteria, business results, includes customers' satisfaction results, financial and market results, human resources results, suppliers' and partners' results, and company specific results. Many companies are using the award criteria to evaluate their own quality programs and implement quality initiatives.[26,28]

In 2000, the Baldrige framework was extended to the healthcare sector. Since then many healthcare organizations have used the framework for self–assessment and performance improvement. In 2005, 33 healthcare organizations applied for the Baldrige award. The award criteria require organizations to show evidence of systems thinking, benchmarking, and comparative results.[29]

Five healthcare organizations that either won the Malcolm Baldrige National Quality Award or had been documented in extensive case studies were documented as sharing a common model of management: they all emphasized a broadly accepted mission, measured performance, continuous quality improvement and responsiveness to the needs of patients, physicians, employees and community stakeholders. These institutions' achievements were viewed as setting a standard for performance accountability and excellence in hospital management, showing how to run healthcare organizations substantially better than is typical and documenting the processes that produce excellence.[30]

4.3.2 European Foundation for Quality Management (EFQM)

The European Foundation for Quality Management (EFQM) Excellence Model is a framework for organizational management systems designed for helping organizations in their drive toward being more competitive. The objective of the EFQM model, proposed in 1992, is to support organizations to achieve business excellence

through continuous improvement and deployment of processes.[27] The effectiveness of EFQM model deployment depends on the selection of an appropriate set of objectives, a strong relationship between the results and enablers, and management focus on their monitoring and reporting.[31]

The EFQM model uses nine basic criteria: five are "enablers" (leadership, policy and strategy, people, partnership and resources, and processes) and four "results" (customer results, people results, society results, and key performance results). According to the model: excellent results in performance, customers, people and society are achieved through leadership driving policy and strategy delivered through people, partnerships, resources and processes.[32] The resulting criteria thus cover both tangible and intangible performance (eg employees' capability, strong relationship with customers, and organizational reputation). Using the model, organizations can develop tangible and intangible-oriented indicators, measure their performance periodically, and develop relevant enablers.[27]

The EFQM model is based on eight principles:[32]

- Results orientation – Organizational actions have to be oriented by the needs of stakeholders (employees, customers, allies, society and those who have economical or non-economic interests in the organization). It is necessary to reach a balance between different interests.
- Customer focus – The customer is the judge of product quality. The organization should focus on satisfying customers' current and future expectations.
- Leadership and constancy of purpose – The management team has to be involved in the development of a culture of excellence. It is necessary to have an entrepreneurial view of the organization's future.
- Management by processes and facts – The excellent organization manages activities as processes. Owners are specifically identified and defined. Activities concerning process improvement are carried out following a quality management system.
- People development and involvement – People are the most valuable asset in organizations. Corporations have to pay increasing attention to shared values, promoting an environment of confidence, responsibility assumption and personal development.
- Learning, innovation and continuous improvement – Correct management of knowledge, experiences, creativity and innovation is necessary for the development of a continuous improvement culture.
- Partnership development – The search for excellence involves mutually beneficial collaboration and cooperative relations. This sort of relationship is based on confidence. Knowledge socialization is essential for creating value in customer service.
- Corporate social responsibility – Ethical principles should inspire organizational behaviour. Ambitious continuous improvement objectives will exceed the limited objectives of compulsory norms.[32]

The EFQM Business Excellence Model framework is used to assess organizations for the European Quality Award that aims to develop awareness of the importance of quality in the global market.[27] In organizations, the EFQM model is used in different ways:[27]

- As a tool for self-assessment
- As a way to benchmark with other organizations
- As a guide to identify areas for improvement
- As the basis for a common vocabulary and a way of thinking
- As a structure for the organization's management system.

Having its foundation in industry, some believe that the approach is not specific enough to cover all areas relevant to health care and that EFQM terminology can cause a barrier. However, the view is presented that a combination

of the management smart evaluation method of EFQM with clinical standards as developed by peer auditing and accreditation systems could generate the potential to deliver excellence in health care.[33]

4.3.3 Canadian Healthcare Excellence in Quality Award (CHEQA) and Canada Awards of Excellence

The Canadian Healthcare Excellence in Quality Award (CHEQA) was created by the Quality Healthcare Network to promote and recognize Canadian healthcare organizations that have demonstrated excellence in the areas of patient safety and overall quality of care. The goals of CHEQA are three-fold:[34]

- To inspire positive change – Help in motivating organizations to share and develop innovative ways to raise the quality of care and the patient experience in their communities
- To recognize excellence – Reward organizations that show dedication to the improvement of methods that lead to better outcomes
- To promote best practices – Build awareness of effective real-world efforts that improve outcomes in patient safety and service excellence.

Applicants are judged, in part, on the following criteria:[34]

- Setting the Aim – The impact on the clinical condition, population, or problem as defined by high volumes, problematic quality or outcomes, high costs, or other indications
- System Improvement – Demonstration of improved clinical outcome or improved quality of life as shown by significant reductions in risk, complications, mortality, patient/client/resident errors, or a noteworthy increase in safety, improved function or independence
- Use of Benchmarks – The degree to which the applicant used benchmarking data (national, regional or internal data) to identify improvement opportunities and establish targets
- Value to the Individual – Safety, well-being or satisfaction of the patient/client/resident in the overall project development, objective, or results
- Replicability – The extent to which the improvement can be replicated as demonstrated by the clarity of the project as a roadmap for others.

The seven criteria used in the Canada Awards for Excellence include leadership, customer focus, planning for improvement, people focus, supplier focus, process optimization and organizational performance, closely mirroring those of the Malcolm Baldrige Award.[35]

4.4 Continuous Improvement Models

4.4.1 Kaizen

Kaizen is a Japanese term for 'change for the better'; the common English term is continuous improvement.[4]

Kaizen means 'good change'. It has two ingredients: one is to train each employee to come to work each day looking for ways to improve the process and/or the product; the second is that all improvements have one purpose in mind, which is to serve the customer.[1]

Kaizen employs a rigorous approach using constant evolution through small measures in their search for perfection. Toyota made it the job of every employee to take small, everyday steps to maximize efficiency and innovation, and to identify mistakes whenever possible, so that problems could be addressed.[36]

Kaizen drives overall excellence through incremental improvements to work processes, based on improving quality, cost and delivery by the elimination of waste (muda). Kaizen is characterized by high-energy problem solving improvement teams that help 'good ideas' become reality.[37] The culture of Kaizen encourages immediate improvement to recognized waste. As such, some of the Kaizen benefit emerges through small changes in daily routines.[37]

A more structured version of Kaizen, sometimes known as a 'Kaizen Event' is a facilitated team-event incorporating the Kaizen practices. A Kaizen Event has focus on a particular improvement problem, with specific expectations for waste elimination or reduction.[37]

4.4.2 Continuous Quality Improvement

Continuous Quality Improvement (CQI) is a management philosophy and methodology which focuses on process and system improvement to add value to the organization and to lessen the need to correct individual mistakes after the fact. It empowers the stakeholders of an organization to analyze and continuously improve the process. CQI emphasizes teamwork with a multidisciplinary approach in problem solving and is customer driven with the customer's preference as the determinant of quality.[17]

CQI comprises an overarching theory of quality management, a set of management practices, and practical methods and tools used to operationalise the theory. Definitions, descriptions and actual implementation of CQI can be extremely varied, resulting in debate over the range of approaches that should be labelled as CQI. The main components of CQI most commonly cited in the healthcare literature are:[33]

- A philosophy of continuous improvement of quality through improvement of organizational processes
- Use of structured problem-solving processes incorporating statistical methods and measurement to diagnose problems and monitor progress
- Use of teams including employees from multiple departments and from different organizational levels as a major mechanism for introducing improvements in organizational processes
- Empowering employees to identify quality problems and improvement opportunities and to take action on these problems and opportunities
- An explicit focus on "customers"- both external and internal.

CQI is an incremental approach toward process improvement. In healthcare, CQI may utilize the plan, do, check/study, and act (PDCA/PDSA) method, quality improvement employee teams, employee recognition and rewards, promotion opportunity, patient satisfaction measures and competitive benchmarking.[40]

4.4.3 Model for Improvement (MFI)

The Model for Improvement (MFI), developed by Associates in Process Improvement, is used by the Institute for Healthcare Improvement as a framework to guide and accelerate improvement work.[39]

The model has two parts:[39]

- Three fundamental questions:
    - What are we trying to accomplish? What are you trying to solve?
    - How will we know that a change is an improvement? How will you know?
    - What change can we make that will result in improvement? What changes will you make?
- The Plan-Do-Study-Act (PDSA) cycle to test changes in real work settings.

The Model for Improvement guides teams through the steps of CQI: identifying areas for improvement, setting measurable aims, identifying changes to the process of care that are likely to result in improvement and using repeated Plan-Do-Study-Act (PDSA) cycles and data analysis to plan and test changes.[39]

The steps in the model are:

- Setting aims: The aim should be time-specific and measurable and should define the specific population of patients or other system that will be affected.
- Establishing measures: Quantitative measures are used to determine if a specific change actually leads to an improvement.

- Selecting changes: Ideas for changes may come from those working in the system, from change concepts or other creative thinking techniques or by borrowing from experiences of others.
- Testing changes: PDSA cycle involves planning the change, trying it, observing results and acting on what is learned.
- Implementing changes: After testing the change on a small scale, learning from each test and refining the change through several PDSA cycles, the change may be implemented on broader scale.
- Spreading changes: After successful implementation, the change can be spread to other parts of the organization or include other organizations.

4.4.4 Institute for Healthcare Improvement Collaborative

The Institute for Healthcare Improvement (IHI) Collaborative approach is designed to help health care organizations make 'breakthrough' improvements in quality, closing the gap between best and usual care. A Breakthrough Series (BTS) Collaborative uses short, action learning cycles to achieve incremental, rapid and locally relevant improvements across a broad range of clinical and practice business issues. Collaboratives range in size from 12 to 160 teams at a time, and have been used extensively across the world. Basic premises of the Collaborative approach are:[41]

- A substantial gap exists between knowledge and practice in health care
- Broad variation in practice is pervasive
- Examples of improved practice and outcomes exist but they need to be described and disseminated to other organizations
- Collaboration of professionals working towards clear aims enables improvement
- Health care outcomes are the result of processes, and
- Understanding the science of rapid cycle improvement can accelerate demonstrable improvement.

4.4.5 Clinical Practice Improvement (CPI) Method

The Clinical Practice Improvement (CPI) method is a framework that allows continuous quality improvement to be applied in a practical way to clinical processes, in order to improve delivery of care. The clinical practice improvement method is broken into five cycles: project, diagnostic phase, intervention, impact and sustaining improvement.[42]

A clinical pathway is a protocol that directs the appropriate use, sequence and timing of treatment, procedures or incidents during hospitalization. Clinical pathways attempt to maximize compliance, minimize costs, increase quality and safety of care, reduce adverse events and increase uniformity of practice.[42]

The CPI framework allows the application of Continuous Quality Improvement (CQI) theory, in a practical way, to clinical processes, in order to improve delivery of care.[42]

4.5 Plan-Do-Check-Act (PDCA) and Plan-Do-Study-Act (PDSA) Models

The Plan-Do-Check-Act (PDCA) cycle was based on Shewhart's work and popularized by Deming. The Plan-Do-Study-Act (PDSA) cycle and Six Sigma's DMAIC method (define, measure, analyze, improve, control) may be viewed as derivations of PDCA.[4]

The PDSA cycle is the most commonly used approach for rapid cycle improvement in health care. This method involves a 'trial-and-learning' approach in which a hypothesis or suggested solution for improvement is made and testing carried out on a small scale before any changes are made to the whole system.[21]

PDSA stands for:[19]

Plan – plan a change or test aimed at improvement

Do – Carry out the change or test (preferably on a small scale)
Study – Examine the results: What did we learn? What went wrong?
Act – Adopt the change, abandon it or run through the cycle again

Users of the PDSA method follow this prescribed four stage cyclic learning approach to adapt changes aimed at improvement. In the 'plan' stage, a change aimed at improvement is identified, the 'do' stage sees this change tested, the 'study' stage examines the success of the change and the 'act' stage identifies adaptations and next steps to inform a new cycle. The pragmatic principles of PDSA cycles promote the use of a small-scale, iterative approach to test interventions, as this enables rapid assessment and provides flexibility to adapt the change according to feedback to ensure fit-for-purpose solutions are developed. Starting with small-scale tests provides users with freedom to act and learn; minimising risk to patients, the organization and resources required and providing the opportunity to build evidence for change and engage stakeholders as confidence in the intervention increases.[43]

In an example of use of PDCA in a clinical setting, the integration of a hospital's quality program morbidity and mortality meetings into a PDCA cycle was shown to result in reduction of the failure rate and improvement of quality of care in medical issues.[44]

4.5.1 4Ps cycle

A variation on the PDCA/PDSA cycle may be the 4Ps cycle which consists of:[45]

- Prepare: ensuring good inputs to the process (material, machines, methods, manpower)
- Perform: process steps well defined, mistake proofed, lean, understood for consistent execution
- Perfect: assessing whether the process performed as planned and the process output is on target
- Progress: leads to improvement in the process and its output based on the reduction of variation from the target.

4.6 Strategic Quality Models

4.6.1 Strategic Quality Management (SQM)

Strategic Quality Management (SQM) is a systematic approach for setting and meeting quality goals throughout the organization. With the development of SQM, managers began to address quality in their strategic planning processes focussing on customer value. The fundamental nature of SQM is to ensure a continuous assessment of internal and external changes with regard to quality, and an adjustment of the competitive approach based on that assessment.[3]

- Phase I: quality mission of the firm is established with the involvement of the manufacturer
- Phase II: development of a quality profile with the considerations of quality mission and external environment comprising competitors and customers perceptions and declaration of a quality policy
- Phase III: listing or modifying long-term and annual quality objectives
- Phase IV: infuse quality at the design stage
- Phase V: compare with the desired performance at the global level.

Strategic quality is seen to go beyond competitive advantage through functional excellence; to be an entire system of thought. To succeed, quality initiatives must be implemented organization-wide because all functions are interrelated. The formulation of such a strategy must involve all management levels. Understanding corporate strategic goals is viewed as more important than technical expertise and education of all staff in the organization is necessary.[22]

4.6.2 Hoshin Kanri

Hoshin Kanri was developed by Yokogawa Hewlett-Packard in the 1970s and was subsequently adopted in the US by Hewlett-Packard, Procter & Gamble, and Florida Power and Light. Hoshin is a strategic quality management system that involves planning, execution and audit, following the cycle "plan, do, check, act". Hoshin planning includes a long-range plan (five to ten year vision), a one-year plan, deployment to departments, implementation, monthly and annual audit.[22]

4.6.3 Congruence Management Business Architecture (CMBA)

Strategic quality management (SQM) is the formulation and deployment of quality management within the overall framework of strategic planning; every quality or related initiative has potential to change, eliminate or create activities. Under a systems framework called congruence management business architecture (CMBA), each such change is evaluated in terms of how it fits in with the process, the business and the environment. It provides a framework of the positioning of the firm, its businesses, its processes and its activities within its business environment to assure congruence between the offerings of the firm and the expectations of the firm's customers. In this framework, the effectiveness of any management method or quality initiative is measured by the degree and speed at which it helps the firm respond to the business environment by focusing the processes and activities towards a common goal.[46]

4.7 Total Quality Management (TQM)

Total Quality Management is a strategy aimed at embedding awareness of quality in all organizational processes.[4] The Japanese Union of Scientists and Engineers (JUSE) defined Total Quality Management as 'a set of systematic activities carried out by the entire organization to effectively and efficiently achieve company objectives so as to provide products and services with a level of quality that satisfies customers, at the appropriate time and price'.[5]

The core principles of TQM are: focus on customers, employee participation and team work, and continuous improvement and learning. TQM has been widely introduced and accepted in manufacturing and service industries including health care. The foundation of ISO-9000 core requirements and MBNQA criteria are developed upon TQM principles.[26]

TQM emphasizes that continuous improvement is a process with customer satisfaction as its ultimate goal. This has generated much interest and the quest for implementation globally. However, to date, surveys show that successes in TQM implementation are only within the range of 20 to 35 per cent of those who initiated the practice.[47]

Causes of failure are generally associated with:[47]

- Resistance of top management to educate themselves regarding TQM
- Erratic ways of quality program implementation
- Jolting but unsustained enthusiasm for TQM
- Inadequate empowerment at all levels
- Management of communication strategies not fully in place
- Quality improvement teams not functioning effectively.

4.8 Process Improvement

4.8.1 Six Sigma

There appears to be little consensus on the definition of the term 'Six Sigma'. From a statistical perspective, Six Sigma is a metric of process measurement symbolized by the Greek letter *s* that represents the amount of variation with a normal data distribution. From a business perspective, Six Sigma could be described as a process

that allows companies to drastically focus on continuous and breakthrough improvements in everyday business activities to increase customer satisfaction.[48]

Six Sigma is a strategy to accelerate improvements and advance performance levels by focusing on characteristics that are critical to customers by identifying and eliminating causes of errors or defects in processes. A six sigma quality level represents a quality level at most 3.4 errors per million opportunities and corresponds to a process variation equal to half of the design tolerances while allowing the process mean to shift as much as 1.5 standard deviation from the target.[26]

Six Sigma recognizes that an error occurs due to a quality problem. Therefore, the error can be eliminated by defining the problem, finding the magnitude and the root cause of the problem by measuring and analyzing the data, and improve by removing the cause of the problem permanently and setting up a control system for preventing any such problems to occur again.[26] The focus of Six Sigma is not on counting the defects in processes, but the number of opportunities within a process that could result in defects so that causes of quality problems can be eliminated before they are transformed into defects.[48]

Although, at its inception, Six Sigma's primary aim was reducing the amount of "defects" in manufacturing processes, its' application today is much more. It encompasses a broader definition of 'defect' — for example, an invoice not paid within 30 days could be considered a defect — and its techniques extend into proactive and retrospective prediction. Because risks are, in effect, 'defects waiting to happen', Six Sigma techniques can be used to reduce, mitigate, transfer, or eliminate them.[49]

Key Six Sigma principles include:[48]

- Relevance and value to customers
- Enabling data-driven decisions
- Understanding how outcomes are related to key outputs and how inputs and key outputs are related to each other (eg, input-output ratio analysis)
- Eliminating waste of action and inaction.
- Working in a team environment across traditional department silos.
- Financial accountability of projects.

Six Sigma combines established methods such as statistical process control, design of experiments and failure mode and effects analysis (FMEA) in an overall framework.[4]

A central aspect of Six Sigma is its specific problem-solving process: define, measure, analyze, improve, and control (DMAIC). DMAIC is a process that guides a specific project team to improve its process using a rigorous, scientific method.[49] DMAIC follows five steps:[19]

- Define: Establish problem statement, governance and team, voice of customer, scope, stakeholders
- Measure: Identify current performance baseline, validate measurement system, define capability and stability
- Analyze: Identify root causes, validate with data, hypothesis testing
- Improve: Identify improvements based on analyze phase, pilot run PDSA cycles, implement solutions, confirm improvements
- Control: Ensure systems and process are in place to sustain new performance

Examples of tools and techniques used by Six Sigma include Pareto analysis, root cause analysis, process mapping or process flow chart, Gantt chart, affinity diagrams, run charts, histograms, quality function deployment (QFD), Kano model, brainstorming, statistical process control (SPC), process capability analysis, suppliers-input-process-output-customer (SIPOC), SERVQUAL, benchmarking, control charts, histograms, root cause analysis, etc.[48]

Six Sigma is a data-driven, customer-centered approach and methodology which is applicable to health care products and services. It is assumed that every human activity has variability and, therefore, reducing variability is the essence of Six Sigma. A health care organization's performance is measured by the sigma level of its' various clinical, operational and other business processes. The aim of Six Sigma is to eliminate defects to six standard deviations between the mean and the nearest customer specification limit.[50]

Six Sigma's potential to achieve quality improvement results from its focus on reducing variation on systems processes. It allows for recognition of error and influences hospital administrators to develop solutions to address this error. The accountability aspect of Six Sigma and its timely ability to identify and solve error is seen as an asset to hospital administrators.[51]

i. Design for Six Sigma (DFSS)

The Design for Six Sigma (DFSS) approach seeks inventive ways of satisfying and exceeding customer requirements and expectations. It seeks to optimize the function of the product/service design and then verify that the product/service meets those requirements specified by customers. DFSS is not only used in the development of new products or research, it is also used for the process improvement of marketing, sales, and service activity.[53] Design for Six Sigma can assist with the creation of new businesses and services that have zero defect thinking imbedded in their operations.[52]

ii. Critical to Quality in Six Sigma (CTQ)

Critical to Quality (CTQ) in Six Sigma represents the product or service characteristics that are defined by the internal or external customers. CTQs usually must be interpreted from a qualitative customer statement to an actionable, quantitative business specification. CTQ is a product or service characteristic that must be met to satisfy a customer specification or requirement.[53]

4.8.2 Toyota Production System (TPS): Lean

The Toyota Production System (TPS) is commonly known as Lean Manufacturing or Lean Thinking. TPS defines quality as "meeting or exceeding predefined standards".[50]

The Toyota method has three cultural themes:[54]

- Seeking to understand and create the right processes for the right results
- Developing staff and adding organizational value
- Continually striving to understand the root cause of problems.

One of the principles of the Toyota Production System is 'learning to see'. Staff are trained how to observe waste in their systems and to understand the true cause of the problem. Staff are then encouraged to generate ideas for improvement and make changes in their own areas of work.[54]

TPS promotes 'learn by doing'. Small problem-solving teams are created to work on 'learning lines' that provide the opportunity for multidisciplinary members to encounter problems so that they can attack the root cause of the problem, and hence improve quality, safety, cost, or responsiveness.[55]

Through the combination of Lean production that addresses the elimination of waste in all its forms and Lean processes that eliminate waste and non–value-added steps in work processes, TPS improves both cost and quality. The underlying concept is that, when a system lacks reliable mechanisms for integrating the individual elements, it can result in ambiguity over exactly who is responsible for what, when and how. In such settings, TPS organizing principles help minimize ambiguity.[55]

A TPS framework specifies how work is to be carried out in such a level of detail that even small deviations from expected outcomes, whether in routine work or in highly complex unique efforts, are evident. When deviations from the 'ideal' are detected, they are promptly investigated and contained. In this approach, information relevant to understanding the problem is fresh and easier to accurately reconstruct than it would be if problem solving were delayed.[35]

The customer, both internal and external, is the focal point of TPS. An internal customer could be a nurse who needs medication from a pharmacy store. An external customer could be a patient in a specific bed who needs something for pain relief. TPS strives to deliver to customers 'exactly what they need, when they need it, every time, defect-free, in a safe environment, at the lowest cost, without waste'.[35]

Some specific Lean concepts include:[39]

- Identify value: What is 'value' from the customer's point of view?
- Understand value stream: Develop value stream (VS) to determine steps, value added, identify waste
- Eliminate waste
- Establish flow: Improve flow, cycle time, value
- Enable pull: Establish process controls and high reliability
- Pursue perfection

Lean is focused on the creation of value through the elimination of seven codified and well-known wastes:[36]

- Overproduction
- Inventories
- Defects
- Motion
- Transportation
- Waiting
- Processing

Common Lean management tools in healthcare include process mapping, value stream mapping, Kaizen improvement events, just-in-time process management, and "5S" principles. The "5S" principles reduce waste by deploying five steps:[40]

- Sort for necessity;
- Simplify the workplace;
- Shine for cleanliness;
- Standardize processes; and
- Sustain standard processes.

The 5s practice is based on the philosophy that personal organization, neatness, cleanliness, standardization and discipline form the foundation for achieving high quality standards in the production of goods and services, in a well-organized working environment.[37]

Another central tenet of Toyota's philosophy is 'genchi genbutsu'. Roughly translated, it means that one must be hands-on with problems. Engineers are encouraged to engage in need-finding exercises before designing cars, talking to customers to find out how to meet their needs better than rival companies.[36]

The '5 Whys' seek to pursue the root causes of any non-valued-added activity and formulate recommendations for improvement. Toyota asserts that a worker must ask 'why' five times in order to get to the bottom of any problem.[30,36]

Lean processes distinguish between value-added and non-value-added activities. The dominant tool is the value stream map that seeks to prevent and correct sub-optimization along the entire value chain.[30]

In the healthcare organization, a model of Lean Thinking builds on a foundation of creating stability and standardizing the process steps involved in providing clinical care. This allows for continuous learning through implementation of the PDSA cycle. The focus of Lean Thinking is to foster an organization that is committed to finding better ways to serve and care for its patients. Workers are encouraged to be mindful of problems that can arise and empowered to explore their work processes further to identify opportunities to improve.[31]

While Lean is not a new concept, it is relatively new to health care. While the fact that 'Patients are not cars' is acknowledged, it is observed that health care is delivered in extraordinarily complex organizations, with thousands of interacting processes, much like the manufacturing industry. Many aspects of the Toyota Production System and other lean tools are therefore believed to apply to the processes of delivering care. Health care organizations are demonstrating that Lean management can reduce waste in health care with results comparable to other industries. Leaders of these organizations emphasize the importance of creating an organizational culture that is ready and willing to accept Lean thinking. Without a receptive culture, the principles of Lean will fail.[29]

The Institute for Healthcare Improvement believes that many management and operations tools in other industries can be applied successfully to health care, that Lean principles hold the promise of reducing or eliminating wasted time, money, and energy in health care, and creating a system that is efficient, effective and truly responsive to the needs of patients.[59]

While there are benefits for its use in health settings, clearly it offers no quick fix. Lean is a learning system with a long-term perspective. Based on experience of applying a Lean approach in French hospitals, the critical challenge for would-be Lean practitioners was to first understand the underlying concepts and tools of Lean Thinking and how they fit in the context of the healthcare consumer, processes and providers.[34]

While Toyota itself has experienced quality problems recently, the core values of the Toyota Lean Method (empowering workers, maximizing efficiency, heeding costumers, rigid adherence to quality and standards, evolution, innovation, asking why) are applicable to health care and should not be discarded hastily. It is observed that there Lean methods offer benefits for health care provided Toyota's mistakes are understood and their pitfalls avoided. It is insufficient to innovate and introduce new processes, including kaizen, in health care; it is important to constantly evaluate the results of interventions and make changes as necessary.[36]

i. Lean Healthcare Transformation Model with Queuing Theory

A Lean health care (LEAN-HC) transformation model integrating queuing theory and Lean methodology was used to improve the dynamic performance of the health care system. The LEAN-HC model used Physician Directed Priority Class Queuing (PDPCQ) to separate emergency patients at triage into major, medium, and minor injury classes. After the patients were separated, the three categories each had a single queue of patients awaiting services delivered in multiple phases. PDPCQ was derived from queuing theory, a mathematical approach applied to the analysis of waiting lines that 'enables mathematical analysis of several related processes, including arriving at the (back of the) queue, waiting in the queue (essentially the storage process) and being served at the front of the queue. The theory permits the derivation and calculation of several performance measures'. Queuing models were used to achieve a balance between capacity and delays. PDPCQ used queuing theory to predict average waiting time, queue length and system utilization.[60]

4.8.3 Lean Six Sigma (LSS)

A combination of Lean/Six Sigma (LSS) may provide synergistic benefits. Both focus on customer requirements, reducing cost and making a positive financial impact. However, a difference between the Lean and Six Sigma is that

they attack different types of problems. Lean focuses the more visible problems in processes such as inventory, material flow and safety, while Six Sigma focuses on the less visible problems related to precision and accuracy in performance.[40,56] Lean seeks out the voice of the customer and then focuses on customer satisfaction while improving the speed of operations and reducing waste. Six Sigma determines the causes of defects and focuses on eliminating process variability.[61]

Some organizations that combine Lean and Six Sigma fall short of their goals because they have made some missteps and encountered psychological inertia when deploying the approach. To avoid these failures and get maximum results, organizations must take into account the differing philosophies of Lean and Six Sigma. In other words, organizations must find the right blend that accentuates the strengths of both.[62]

Improvements will occur in organizations that practice either Lean or Six Sigma but these improvements may begin to level off at a certain point in time. With Six Sigma alone, the leveling off of improvements may be due to the emphasis on optimizing measurable quality and delivery metrics, but ignoring changes in the basic operating systems to remove wasteful activities. With Lean alone, the leveling off of improvements may be due to the emphasis on streamlining product flow, but doing so in a less than scientific manner relating to the use of data and statistical quality control methods. A Lean Six Sigma (LSS) organization is believed to have the ability to capitalize on the strengths of both Lean and Six Sigma.[63]

A LSS organization would include the following three primary tenets of Lean management:[63]

- Incorporate an overriding philosophy that seeks to maximize the value-added content of all operations
- Constantly evaluate all incentive systems in place to ensure that they result in global optimization instead of local optimization
- Incorporate a management decision-making process that bases every decision on its relative impact on the customer.

A LSS organization would include the following three primary tenets of Six Sigma:[63]

- Stress data-driven methodologies in all decision making, so that changes are based on scientific rather than ad hoc studies
- Promote methodologies that strive to minimize variation of quality characteristics.
- Design and implement a company-wide and highly structured education and training regimen.

Because LSS is a system for improving the ways in which a business operates (both in its core business and within its supporting organization), LSS must be cognizant of the economic factors and external environment within which the organization competes. Factors affect the ability of a competitive organization to maintain or improve its competitiveness in the face of substantial changes occurring in the economy and marketplaces; these need to be closely assessed and the practice of LSS adapted accordingly. Four implications for LSS practitioners are:[64]

- Value definition – the definition of value will become more ambiguous and will encompass multiple considerations, including those that would be classified as financial, tangible, and intangible
- Risk factors – global operations, markets, and additional stakeholders will increase the number of potential risks and uncertainties
- Workforce considerations – the workforce participating in improvement efforts and those affected by the resulting implementations will be geographically, educationally, and culturally diverse; and the type and nature of jobs performed in the workplace will change
- Regulatory environment – the number and scope of international standards and regulations will increase and would be expected to change frequently.

A LSS model implemented in a perioperative environment integrated multiple data sources of defects and used a multidisciplinary team to provide central multidisciplinary oversight to analyze defects and create and sustain

quality improvement projects. Lean Six Sigma methodologies, through comprehensive and ongoing training, were found to be adaptable to the clinical environment with little modification needed. They helped provide a consistent framework in which to incorporate input, output, and feedback mechanisms while organizing a complex perioperative process. This quality and patient safety management model showed the enormous inherent value.[65]

i. Healthcare Lean Six Sigma System (HLS³)

A healthcare quality model called 'Healthcare Lean Six Sigma System' (HLS³) integrated Lean and Six Sigma in the healthcare setting. HLS³ bridges the service gaps between health care providers and patients, while balancing the needs of health care managers. HLS³ delivers by capitalizing on the benefits of Lean speed and Six Sigma's principle of high quality. In this model, the first stage of health care QI is to identify the QI goal by hearing the Voice of Customer (VOC) or the patient. The second stage is to analyze the current status of the targeted process. This involves collecting data to obtain the VOC and Voice of Provider (VOP). The QI team can then identify the problem and begin to determine its root causes. The third stage is to develop problem-solving countermeasures. First, the QI team generates information by identifying all the measurable characteristics of the health care delivery/service that they perceive are related to meeting the patient requirements. Then the QI team implements the measures and confirms the results by using performance indicators. The last stage is to develop a follow-up plan and deploy the knowledge throughout the organization.[66]

4.8.4 Process Excellence (PEx)

PEx is a structured methodology described as being results oriented, project focused and customer value driven. PEx includes the principles and toolsets of Lean, Six Sigma, and Design Excellence. Design Excellence is used to drive the design of a new product, service or work space to optimize process flow and meet customer expectations with minimal waste and defect opportunities. PEx seeks to eliminate process variation and waste and deliver value to customers faster with appropriate resources. It purports that Six Sigma, by itself, is not able to impact exponential improvement without incorporating principles from Lean. Lean drives optimal efficiencies by identifying and eliminating as much waste or non-value-adding activities as possible and establishing standard work. The view presented is that Lean coupled with Six Sigma tools drives decision-making by data and metrics and provides a mechanism to quantify the potential for variation, defects and risk as well as value-added and resource optimization before implementing actual changes.[66]

4.8.5 The Productive Series (Releasing Time to Care)

The Productive Series (sometimes also known as Releasing Time to Care™) is a series of service improvement programs developed by the NHS Institute for Innovation and Improvement for healthcare settings. The Productive Series helps staff to identify time wasting activities, duplication and inefficiencies so that teams can stop doing things that are wasteful and take time away from caring for patients, thereby contributing to quality, reliability and safety of patient care. Simple things like protecting meal times, working with patients individually on their care plan, protecting drug rounds, preventing interruptions at staff handovers and streamlining discharge processes have reduced errors, improved safety and helped patients to get the care that they need in a timely way with the right support. It is stated that, on average, staff have freed up to 20-30% of additional time which can have a huge impact on improving the quality of care for patients by focussing on important improvements including:[67]

- Safety and infection control
- Improving nutrition and hydration
- Better co-ordinated care across departments
- More focused time with patients and their families
- Improving ward and medicine rounds
- Using theatres better to reduce waiting lists.

4.9 Business Change Models

4.9.1 Business Process Change (BPC))

Business process change (BPC) is an organizational initiative to achieve improvement in performance (eg quality, responsiveness, cost, flexibility, and other critical process measures) through changes in the relationships between management, information technology, organizational structure and people. For success, a BPC requires a strategic initiative where top managers act as leaders in defining and communicating a vision of change. The organizational environment, including a ready culture, willingness to share knowledge, balanced network relationships and capacity to learn, facilitates the implementation of prescribed process management and change management practices. Process and change management practices, along with the environment change, contribute to better business processes and help in securing improved quality of work life, both those required for customer success and for achieving measurable and sustainable competitive performance gains.[68]

4.9.2 Business Process Re-engineering (BPR)

Business Process Reengineering (BPR) is the analysis and redesign of workflow within and between enterprises.[3] BPR's management approach is aimed at 'clean slate' improvements (abandoning existing practices).[4]

4.9.3 Business Process Management (BPM)

The Association of Business Process Management Professionals defines Business Process Management (BPM) as 'a disciplined approach to identify, design, execute, document, measure, monitor and control both automated and non-automated business processes to achieve consistent, targeted results aligned with an organization's strategic goals. BPM involves the deliberate, collaborative and increasingly technology-aided definition, improvement, innovation and management of end-to-end business processes that drive business results, create value and enable an organization to meet its business objectives with more agility'.[69]

4.10 Reliability Models

4.10.1 Deep Quality Concept (DQC)

The Deep Quality Concept (DQC) asserts that quality of any product and/or service depends significantly on knowledge. To be considered as reliable, knowledge concerning the organization processes has to be identified, and then it has to be formalised as much as possible. It also has to be stored in a way that it is easily accessible. While formalization of some knowledge is trivial, for example it can be relatively easily expressed and formalized in the form of written documents such as texts, formulas and/or drawings and stored in books, hand-books and manuals, to formalize and store tacit knowledge, special mechanisms are required. In the context of domain dependent knowledge, that especially refers to the tacit dimension of expert knowledge. Given that expert knowledge is often key to the output quality of a product and/or service, and that experts often lack motivation, skills and time to document their expertise, the conclusion is that mechanisms for capturing, representing and storing of such knowledge are necessary and integral parts of quality systems. Quality systems that have not included mechanisms for continuous integration of formalized knowledge cannot be considered as effective and reliable. The reasons for that are:[10]

- Knowledge and experience of an individual could be insufficient for a reliable and complete solution
- Sufficiently competent people are not always available or may be too expensive
- There is uncertainty always connected with humans.

DQC introduces the specific mechanisms aimed at formalizing the domain knowledge, particularly tacit expert knowledge (that is often referred to as "deep knowledge" given that it is mainly based on experience); and also incorporating other concepts from areas usually skipped out from traditional approaches. In other words the

approach emphasises the need for deep analysis of all dimensions of quality and relevant concepts, techniques and tools of various research areas, and aims at integrating them into quality systems.[10]

The model explains clearly what are the place and the role of high quality databases and formalized knowledge within quality management systems. Particular attention is put on standardization of domain concepts and domain tacit knowledge. Thus, the DQC model expands other systems, as for example ISO 9001 and TQM model, in a way that systematically involves knowledge and concepts related to knowledge in the field. According to this approach knowledge management and formalization are viewed at as one of the fundamental parts of any quality system, as well as prerequisite for reliability of quality. Therefore the approach represents the important shift in the relation to the current approaches.[10]

The core concepts of the DQC model are:[10]

- Standardization of domain concepts
- Processes specifications
- Knowledge specifications related to processes
- Data on individual educational history, knowledge and background
- Expertly designed databases and MIS
- Systematic recording of relevant data and information
- Knowledge synthesis and representation
- Knowledge bases and repositories
- Involvement of people and teamwork
- Fair and motivating managerial mechanisms.

The core values of DQC are:[10]

- Knowledge and expertness
- Creativity and integrity
- Social awareness.

These concepts and values, along with others already included in current quality management models, will lead to the quality DQC model's four dimensions:[10]

- Business results.
- Customer satisfaction.
- People satisfaction, development and health.
- Positive impact on society and environment.

4.10.2 Knowledge Management

Knowledge Management is a managerial approach to address the issue of patient safety. The knowledge-based view of organizations suggests that organizational performance results from knowledge management. One knowledge-based view theory proposes a managerial problem-solving perspective. This theory is based on the central role of the leader in implementing such knowledge-building practices as the creation of new knowledge resources, choice among problems that yield desirable knowledge, solution search that optimizes benefits, integration of existing knowledge, and pursuit of solutions by market, bureaucratic, or consensus-based organizational forms. From this perspective, the effective deployment of knowledge management practices by healthcare leaders is the critical link between antecedents and outcomes in resolving medical events and exploiting opportunities.[11]

4.10.3 Human Quality Management (HQM)

Human Quality Management (HQM) is based on the philosophy that health service leaders must recognize that they are a model of quality, as such, have responsibility to ensure that the working environment is safe and free from distractions that place patients at risk. Internal quality management is about integrity and credibility as a leader. Cultivation of the leader's internal quality management is partially dependent upon the alignment between the leader's personal/professional values and those of organization. Another aspect of internal quality management is the practice of mindfulness: being in the here and now is critically important for the delivery of safe, high quality care.[70]

The three prongs of HQM are:[70]

- Internal quality management: Model what you expect
- A-B-C model of HQM: Dissect the triggers (antecedents or A) of the behaviors (or B) that represent major obstacles and the effects (consequences or C) of the behaviors
- Prochaska's model of behavior change: Planning and implementing the intervention

4.11 Human Resource Models

4.11.1 High Performance Work Practices (HPWP) or High Performance Work Systems

Evidence-based human resource or management practices that may contribute to organizational performance have been commonly labeled High Performance Work Practices (HPWPs). Collections of HPWPs used together are often referred to as high-performance work systems or subsystems. In HPWP, emphasis is on attraction, selection, development and retention of personnel, with some definitions also including areas of employee involvement/ decision latitude and leadership practices such as linking training to organizational needs and use of succession planning/internal labor markets. The HPWP model's work practices are grouped into four subsystems:[8]

- Staff engagement,
- Staff acquisition/development,
- Frontline empowerment, and
- Leadership alignment/development.

The model described how these subsystems may interact with one another and may affect organizational and employee outcomes, thus providing an organizing framework by which to inquire about work practices in health care settings.[8]

4.11.2 Strategic Human Resource Management

For healthcare quality management systems, Strategic Human Resource Management (HRM) has recently received greater attention. Employee commitment is critical to maintain quality program success. A study of healthcare employee commitment revealed key predictors are organizational support, job skill enrichment, quality control, and a culture of continuous learning. From research on the not-for-profit sector, employee commitment is found to be enhanced by organizational vision, effective communication, and internal marketing of organizational values to employees. Relationships exist among healthcare error sources, error reduction barriers, quality management processes, quality management practices, strategic HRM, quality program results, and sustainable competitive advantage.[9]

4.11.3 High Commitment Work Practices (HCWP)

The High Commitment Work Practices (HCWP) perspective emphasizes employee empowerment and progressive practices in selection, training, rewards, recognition, information sharing, team-building and socialization. Studies of HRM systems in steel mini-mills concluded that a commitment-based HRM system results in higher productivity,

lower scrap rate and lower employee turnover. To achieve a competitive advantage, HCWP are highly correlated to customers' ratings of service quality. In studies of HCWP, such as progressive employee selection, training, skill development, and motivation, there were positive associations with perceived firm performance and corporate financial performance. Employee empowerment and communication practices enhanced employee trust. Progressive selection and training practices improved perceived organizational and market performance.[9]

4.11.4 Total Relationship Management (TRM)

The Total Relationship Management (TRM) approach emphasizes that patient care and safety is a complex activity which requires that healthcare professionals work together in an effective manner. Evidence reveals that these professionals do not collaborate well together. The TRM approach focusses on 'totality' of the internal and external factors and functions, qualities and relationships.[7]

Perceived quality of interaction and communication reflects a patient's level of overall satisfaction. The interaction process between the provider and receiver of a service is influenced by the atmosphere in a specific environment where they cooperate and operate. The 5 Qs model is presented as being more comprehensive and incorporates essential and multidimensional attributes which are missing in the other models, for example, the infrastructure, atmosphere and the interaction between the patients and the health-care staff. The atmosphere influences by the characteristics of the partners involved and the nature of the interaction itself. The atmosphere can affect the perceived service quality by improving it or by making it worse.[7]

TRM's 5 Qs can be used as a tool to identify the shortcoming of a health-care institution, identify and reduce the medical errors which lead to the increase of the patient safety, and doctor and patient satisfaction. The five Qs are:[7]

- Q1: Quality of object – the technical quality (what patient receives), measures the treatment itself, the main reason of why a patient is visiting a hospital
- Q2: Quality of processes – the functional quality (how the health-care provider provides the core service (the technical)), measures how well health-care activities are being implemented; eg waiting times and speed of performing the health-care activities.
- Q3: Quality of infrastructure – measures the basic resources which are needed to perform the health-care services: the quality of the internal competence and skills, experience, know-how, technology, internal relationships, motivation, attitudes, internal resources and activities and how these activities are managed, co-operated and co-ordinated.
- Q4: Quality of interaction –measures the quality of information exchange (eg the percentage of patients who are informed when to return for a check-up, journal systems, amount of time spent by physicians or nurses to understand the patient's needs, etc.), financial exchange and social exchange, etc.
- Q5: Quality of atmosphere – the relationship and interaction process between the parties are influenced by the quality of the atmosphere in a specific environment where they cooperate and operate. The atmosphere indicators should be considered very critical and important because of the belief that lack of frankly and friendly atmosphere explains poor quality of care.

4.11.5 Professional Practice / Relationship Based Care Nursing Model

The Professional Practice / Relationship Based Care Nursing Model was premised on 8 shared beliefs:[71]

- It is a privilege to care for those who have entrusted their care to us
- The patient is the centre of our universe
- Care should be seamless
- Healthful work environment
- Simplification of work processes

- One vision/voice for nursing
- There should be a mechanism through which nurses can express and manage their practice with a higher level of professional autonomy.
- Nursing staff should seek out opportunities to build relationships with patients and families, physicians and other colleagues.

4.12 Integrated Models

The literature provides examples of organizations that have customized their quality management approaches by integrating various safety and quality models.

4.12.1 Kaiser Permanente (KP) Performance Improvement Model

The Kaiser Permanente Performance Improvement Model incorporates the principles and systems approach based on the attributes of a high performing organization and integrates Lean, Six Sigma and IHI's Model for Improvement. Six areas are recognized as being needed to build capacity in order to achieve breakthrough performance:[19]

- Leadership
- Systems
- Measurement
- Learning
- Capacity
- Culture

4.12.2 Auckland District Health Board Integrated Approach to Improvement

Auckland District Health Board's Integrated Approach to Improvement incorporates the principles and systems approach based on the attributes of a high performing organization and integrates Lean, Six Sigma and IHI's Model for Improvement. Six areas, based on Baldrige Performance Excellence Framework, are recognized as being required to build organization capability to achieve sustainably superior results:[19]

- Leadership
- Patients & community
- Improved processes
- Strategy & planning
- Engaged workforce
- Measurement & analysis

4.13 Customer Focus Models

4.13.1 Experience Based Design (EBD)

Experience based design (EBD) is a user-focused design process, the goal of which is to make user experience accessible to the designers, allowing them to conceive of designing experiences rather than designing services. Experience is defined as 'how well people understand it, how they feel about it while they are using it, how well it serves its purpose, and how well it fits into the context in which they are using it'. By identifying the key moments and places (moments of truth or touch points) where people come into contact with the service and where their subjective experience is shaped, and therefore where the desired emotional and sensory connection needs to be established—and working with the front-line people who bring alive those various touch points in the journey—it is possible to begin designing experiences rather than processes.[13]

On the present 'continuum of patient influence' starting from complaining and information giving, to listening and responding, through consulting or advising, to full participation and involvement—all of which are currently found within the lexicon of healthcare improvement—EBD is one step on, being about co-designing services. In this, the traditional view of the user as a passive recipient of a product or service gives way to the new view of users as the co-designers of that product or service, and integral to the improvement and innovation process.[13]

A recent report in England suggests that the health service there could often seem to be designed around the needs of healthcare staff rather than patients, perhaps signifying a gap between the rhetoric or ideology and the practice. In most countries, despite the longevity of the 'patient involvement' concept, healthcare systems are still not putting patients first.[13]

Placing the experience goals of patients and users at the centre of the design process and on the same footing as process and clinical goals means that design systems, pathways and processes, concepts that have dominated health service design work for nearly a decade, need to move over and make room for it, science and the objective sitting alongside the aesthetic and the subjective. It is not a question of replacing them—there will be as great a need as ever for process mapping, care pathways and other well-established methods and tools as before—but of expanding and enriching the concept of service improvement, and with it our storehouse of methods and techniques.[13]

Five differences between where things are now and where they could be if concepts of user participation and EBD were incorporated into future healthcare designs are:[13]

- Rather than using user groups to feedback suggested changes in healthcare processes and services, EBD is a joint venture that involves users and professionals working together over a period and throughout the change process as the co-designers of a service.
- The focus of experience design is not so much on user views, attitudes, needs and perceptions (although all come into it) as user experiences—creating not just a service but a whole experience that appeals and works on a cognitive and emotional level.
- The focus is on designing experiences, not processes or systems or just the built environment. In contrast with traditional process mapping techniques, the focus here is on the subjective pathway (the touch points) rather than the objective pathway, the internal rather than the external environment.
- Getting at experiences is a specialised activity that needs to be learnt and practised. What often poses as experience research is actually little more than a conversation that anyone may have had, and words and stories without analytical frameworks do not speak for themselves. It is how they are to be used in the discovery and change process that is important.
- In interpreting experiences, the main challenge is to understand how the interface between the user and service is shaped. Most traditional service improvement methods, including those in healthcare, do not concern themselves with that relationship. It is important to appreciate that usability and interactivity are not only about how "nice" the service feels but also about the two other basic elements of design: safety and functionality

4.13.2 Stakeholder Theory of Quality Management

The Stakeholder Theory of Quality Management is based on a detailed analysis of the purpose of the firm (or business enterprise) and the crucial role that stakeholders play in the achievement of that purpose. Growing evidence is now available to show that the success (and indeed the long-term survival) of an organization can be affected by the way in which management engages with stakeholders. This means that any theory concerned with quality management must look beyond the internal operations of the organization and consider the nature and management of its relationships with all relevant stakeholders.[6]

4.13.3 Quality Function Deployment (QFD)

Quality function deployment (QFD), also known as the House of Quality approach, focuses on customer wants or needs in the (re)design of a product or service.[4] The QFD process entails determining customer requirements and translating these requirements into product attributes that each functional area can understand and act on. The process involves constructing one or more matrices through which the customer perspective is converted into a product or process how-to. A product how-to is a set of pre-defined activities to achieve customer needs.[72]

The QFD approach with its focus on transferring the "Voice of the Customer" through technical requirements into measurable parameters has captured the imagination of many companies. Once all the customers are identified, statements of their individual needs are required to start QFD.[73]

4.13.4 Always Events Framework

The IHI Always Events framework is a strategy to help healthcare leaders identify, develop and achieve reliability in a person and family centered care delivery process. An Always Event is a clear, action oriented and pervasive practice or set of behaviors that provides the following:[74]

- A foundation for partnering with patients and their families
- Actions that will ensure optimal patient experience and improved outcomes
- A unifying force for all that demonstrates an ongoing commitment to person and family centered care

Always Events are aspects of the patient experience that are so important to patients and families that healthcare providers must perform them consistently for every patient, every time. An Always Event meets the following criteria:[74]

- Important: Patients and families have identified the experience as fundamental to their care. Any event that is successfully implemented will have a meaningful impact on improving the patient experience.
- Evidence-based: The experience is known to be related to the optimal care of and respect for the patient.
- Measurable: The experience is specific enough that it is possible to accurately and reliably determine whether or not it occurred; therefore Always Events are translated effectively into operations.
- Affordable and Sustainable: The experience can be achieved and consistently sustained by any organization without substantial renovations, capital expenditures or the purchase of new equipment or technology.

4.13.5 Listening into Action (LiA) Optimal Framework

Listening into Action™ (LiA), implemented in recent years in many British health trusts, is a systematic, comprehensive, outcome-oriented approach to engage and empower clinicians and staff around any challenge. LiA is led and sponsored by the Chief Executive, supported by clinical and operational leaders who, together, 'navigate the journey' of adoption and spread over an initial 12 month period and beyond so that it becomes embedded as 'the way we do things around here'. LiA is a strategic vehicle for transformation. It brings together the powerful combination of top level, unwavering commitment with an engaged and empowered workforce.[75]

The LiA Optimal Framework™, developed 'by the NHS for the NHS', provides a comprehensive way to tackle improvements in specific service areas, delivered through the direct engagement of the people who work there. It brings together a holistic view of the most likely opportunities for improvement based on best practice, input from NHS staff and focused development work. This is combined with the '7 Simple Steps' for engaging all the right people who, between them, have the ability, influence and know-how to make it happen.[75]

The LiA Optimal Framework focuses on three dimensions of change:[75]

- Quality and safety
- The patient experience

- Working together.

Teams are coached through a 'journey', which begins with a clear view of how they are performing today, and takes them through a step-by step process to engage the right people, identify the biggest opportunities for improvement and deliver measurable outcomes for the benefit of patients, staff and the Trust. Feedback from staff about the framework is simple, easy to use, and provides everything they need to drive change for themselves, thus putting them in the driving seat while also giving Trust leadership a 'methodology' for enabling change. It leverages use of other improvement initiatives such as LEAN and the Productive Series by contextualising and sharpening the way in which they are used and applied.[75]

LiA empowers teams to drive forward positive changes, shifts the culture and style of leadership, reenergises staff who previously felt helpless and unable to act, challenges existing assumptions, eliminate wasteful or irrelevant activities that provide no value to patients. Staff come together to decide what 'great' would be like, what gets in the way of them achieving that today, and what they will change together to address that. They take ownership of and pride in delivering the outcomes they want to see, using simple action plans and a variety of tools to help them, and their achievements are held up as inspiration to others.[75]

5.0 Safety Models and Concepts

According to the Institute of Medicine of the National Academies (IOM) in the US, patient safety is 'freedom from accidental injury due to medical care, or medical errors', with medical error being defined as 'the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim... [including] problems in practice, products, procedures, and systems'. Patient safety has traditionally been considered as one among many dimensions of quality of care, but it is increasingly being seen as absolutely key to quality overall. As a consequence, the policy debate concerning patient safety has developed in parallel to mainstream quality of health care initiatives and patient safety forms an essential dimension of quality of health care.[14]

The 2000 IOM report explains that 'safety is a critical first step in improving quality', and patient safety is defined as 'a subset of overall quality-related concerns'. The IOM report further describes the relationship of safety to quality management when it states that 'making environments safer means looking at processes of care to reduce defects in the process or departures from the way things should have been done. Ensuring patient safety, therefore, involves the establishment of operational systems and processes that increase the reliability of patient care'.[11]

5.1 Safety Culture

The safety culture of an organization has been defined as 'the product of individual and group values, attitudes, and perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management'; in other words, 'doing the right thing even when no one is watching'.[76]

A Safety Culture is one in which safety has a special place in the concerns of those who work for the organization. Safety Cultures can be distinguished along a line from 'pathological', caring less about safety than about not being caught, through 'calculative', blindly following all the logically necessary steps, to 'generative', in which safe behaviour is fully integrated into everything the organization does. A Safety Culture can only be considered to exist in an organization if at the later stages of this evolutionary line.[77]

The term Safety Culture encompasses all of the attitudes, perceptions, behaviors, competencies, and values that contribute to an organization's prioritization of and commitment to safety. The term 'Safety Climate' refers to the measurable aspect of an organization's safety culture and focuses on perceptions and attitudes, although the two

terms are often used as synonyms. In high-risk industries, safety climate describes a group's perceptions of behaviors and procedures as they relate to the overall priority of safety in the workplace.[78]

A Safety Culture encompasses the commonly held perceptions and beliefs of an organization's members pertaining to the public's safety and can be a determinant of the behavior of the members. A healthy Safety Culture relies on a high degree of trust and respect between personnel and management and must therefore be created and supported at the senior management level. A healthy Safety Culture actively seeks improvements, vigilantly remains aware of hazards and utilizes systems and tools for continuous monitoring, analysis and investigation. Other characteristics of a healthy Safety Culture include a shared commitment by personnel and management to personal safety responsibilities, confidence in the safety system, and a documented set of rules and policies. The ultimate responsibility for the establishment and adherence to sound safety practices rests with the management of the organization. A Safety Culture cannot be effective unless it is embedded within an organization's own culture.[5]

Safety Culture aims to keep the collective mind of the organization focused on safety. A strong Safety Culture begins with leadership commitment to making safety a priority in every decision. The 'belief' part of safety must therefore be addressed, understood, and corrected if necessary, and this is the domain of Safety Culture.[79]

James Reason stated that Safety Culture encompasses the following aspects:[79]

- Reporting Culture, which encourages employees to divulge information about all safety hazards that they encounter
- Just Culture, which holds employees accountable for deliberate violations of the rules but encourages and rewards them for providing essential safety-related information.
- Flexible Culture, which adapts effectively to changing demands and allows quicker, smoother reactions to off-nominal events
- Learning Culture, which is willing to change based on safety indicators and hazards uncovered through assessments, audits, and incident analysis.

A Safety Management System (SMS) and Safety Culture are inter-dependent: SMS embodies the competence to achieve safety, whereas Safety Culture represents the commitment to achieving safety.[79]

5.1.1 Just Culture

A Just Culture supports learning from unsafe acts in order to improve the level of safety awareness through the improved recognition of safety situations and develop conscious articulation and sharing of safety information.[80]

A Just Culture balances the need for an open and honest reporting environment with the end goal of a quality learning environment and culture. While the organization has a duty and responsibility to employees (and ultimately to patients), all employees are held responsible for the quality of their choices. Just culture requires a change in focus from errors and outcomes to system design and management of the behavioral choices of all employees.[24]

There are a number of benefits of having a Just Culture versus a blaming culture (or indeed a no-blame culture). Three main benefits have been described as:[80]

- Increased safety reporting
- Trust building
- More effective safety and operational management.

The process of clearly establishing acceptable versus unacceptable behavior is done in a collaborative environment bringing together different members of the organization, resulting in common understanding of where the lines are drawn for punitive actions and enhancing the trust that is at the core of a Just Culture.[80]

After identifying an adverse event or near miss, the investigation procedure technique becomes paramount. A 3-step process is described:[24]

- The first step analyzes the individual caregiver's actions via 5 measures: impaired judgment, malicious action, reckless action, risky action, and unintentional error.
- The second step determines if other caregivers with similar skills and knowledge would react the same way in similar circumstances.
- The final step is the important determination of whether the present system supports reckless or risky behavior and thus requires redesign.

5.2 Safety Management System (SMS) Framework

A safety management system is a systematic, precise and proactive process for managing safety risks. As with all management systems, a safety management system provides for goal setting, planning and measuring performance. A safety management system is woven into the fabric of an organization. It becomes part of the culture; the way people do their jobs.[81]

The universally accepted SMS framework includes four main components and twelve elements, representing the minimum requirements for SMS.[81] The four components and twelve elements that comprise the International Civil Aviation Organization's (ICAO) Safety Management System (SMS) framework are:[3]

1. Safety policy and objectives
    - Management commitment and responsibility
    - Safety accountabilities
    - Appointment of key safety personnel
    - Coordination of emergency response planning
    - SMS documentation
2. Safety risk management
    - Hazard identification
    - Safety risk assessment and mitigation
3. Safety assurance
    - Safety performance monitoring and measurement
    - The management of change
    - Continuous improvement of the SMS
4. Safety promotion
    - Training and education
    - Safety communication.

Managing safety means managing safety risk which means trying to prevent bad things from happening, or if something does go wrong, working to minimise the consequences of the event. Safety management is about accepting that things will go wrong and reactively, proactively and predictively controlling risks to a level that is acceptable. Safety management can help predict potential risks, take appropriate action and measure how well risk controls are working. It can give the business information needed to manage risks in other areas such as finance or productivity.[81]

5.3 Staff Engagement in Safety

5.3.1 Patient Safety Walkrounds (PSWR)

For organizations at any stage of development, senior leaders are encouraged to use weekly Patient Safety Leadership WalkRounds (PSWR) to demonstrate their organization's commitment to building a culture of safety.

WalkRounds are conducted in patient care departments, such as the emergency department, operating rooms, and radiology, nursing units, the pharmacy, and laboratories. They provide an informal method for leaders to talk with front-line staff about safety issues in the organization and show their support for staff-reported errors.[82,83] The intent of WalkRounds is to implement a patient safety infrastructure that bridges the gap between leaders and frontline caregivers.[84] The PSWR process is a situational awareness tool that helps management periodically assess new or unresolved vulnerabilities that may affect safety and care quality on the unit. Unit-based PSWRs help identify safety concerns at the microsystem level while improving communication about safety events across units and to hospital leaders in the macrosystem.[85]

Executive WalkRounds (EWRs) have been shown to have a positive effect on the safety climate attitudes of nurses who participate in the walkround sessions.[86] By using Patient Safety Leadership WalkRounds weekly, senior leaders of health care organizations can demonstrate to staff the organization's commitment to building a culture of safety.[83]

Leaders who focus solely on safety during WalkRounds are more successful at creating a culture of safety than those who use them as an opportunity to discuss a variety of topics such as budgets and patient satisfaction.[82,83] The reported end result is a significant improvement in frontline caregiver assessments of patient safety and a narrowing of the apparent disconnect between front line staff and managers.[84]

Specific objectives of Patient Safety Walkrounds (PSWR) are to:[85]

- Provide a forum for frontline staff to freely report and discuss patient safety problems with unit local leaders
- Improve teamwork and communication within and across units
- Develop a supportive environment in which staff and leaders brainstorm on potential solutions.

Seven steps are required for effectively implementing WalkRounds:[84]

- Preparation - Ensure commitment and regular participation by leadership, secure dedicated resources from quality and safety departments and clearly communicate process, scheduling and feedback mechanisms for the rest of the organization
- Scheduling - Set WalkRounds months in advance and accommodate schedules of executive team members, supporting patient safety staff and other participants
- Conducting WalkRounds - Decide where to conduct the sessions. Sessions should include opening and closing statements and a series of specific questions
- Tracking - Set up a robust process for tracking and ranking collected data
- Reporting - Share WalkRounds data with a multidisciplinary committee so that action items may be assigned to management personnel
- Feedback - Establish a clearly delineated and formal structure for feedback to frontline providers who participate in WalkRounds and to executive boards about findings and actions taken to address them
- Measurement - Evaluate whether WalkRounds are effective in improving the organization's culture.

5.3.2 Comprehensive Unit Based Safety Program (CUSP)

The Comprehensive Unit Based Safety Program (CUSP) provides a structure whereby a health care organization can develop a broad strategy to improve safety, yet is flexible enough to respond to staff in individual care areas. As part of CUSP, a senior executive adopts a work area and actively participates in safety efforts with staff. Staff in each work area are asked to learn from one defect per month. Department and hospital leaders learn from one defect per quarter using a structured tool. The goal is to move away from just reporting and superficially reviewing multiple hazards to focusing intently on a few and mitigating the hazards by redesign of the system in which work

is performed. In addition, CUSP asks safety teams to implement tools, such as daily goals and morning briefings to help improve safety culture.[87]

This model:[87]

- Identifies evidence-based interventions that improve the outcome
- Selects interventions with the most impact on outcomes and converts to behaviors
- Develops measures to evaluate reliability
- Measures baseline performance, and
- Ensures patients receive the evidence-based interventions.

5.4 High Reliability Organizations (HRO)

Complex systems such as manufacturing and air travel have used reliability principles successfully to help evaluate, calculate and improve their overall reliability. Reliability principles, used to design systems that compensate for the limits of human ability, can improve safety and the rate at which a system consistently produces desired outcomes.[88]

High-reliability organizations (HRO) are those that operate in an environment of high hazard but, from a statistical standpoint, do not have mishaps where these hazards cause a tragedy. High-reliability organizations are those where lines of communication remain open such that whoever has a critical piece of information is expected to communicate it to whomever needs this information, unfettered by barriers of hierarchy, seniority, title, pay grade, gender, or ethnic background. There is a general acknowledgement among the members of the organization that a mishap can happen at any time given the right set of circumstances and that only through a constant mindfulness that no person or organization is perfect can the risk of mishap be minimized. It is this desire to achieve perfection while at the same time recognizing that a mishap can happen that enables high-reliability organizations to post impressive results.[89]

HROs have been defined in terms of their results—namely, highly predictable and effective operations in the face of hazards that can harm hundreds or thousands of people at a time. In many organizations, reliability is achieved by simplifying and standardizing operational tasks and by anticipating and defending against organizational disruptions. Industries with more complex, interdependent, unpredictable, and unforgiving technologies, whose frontline experts know more about their work than do their supervisors, cannot rely solely on a factory model of "divide and monitor". This is the situation in much of health care which is challenged by variability of individual patients, incomplete evidence bases, rapidly evolving technologies, and shifting financial and regulatory climates. HROs are characterized by a constant wariness by employees at every level, a willingness to shift decision making to knowledgeable experts including frontline employees who know the immediate situation and need to respond promptly, a reluctance to simplify or explain away problems, sensitivity to operational personnel and details, and willingness to make investments in training to strengthen the ability of employees to improvise and learn from experience. HRO theory offers design principles such as training and giving discretion to frontline employees, avoiding hierarchy and formalization that inhibits flexibility, and maintaining slack resources, but more specificity is given to cultural values and practices such as mutual respect, heedfulness, collective mind, learning from experience, improvisation, sense making and maintenance of doubt.[90]

High-reliability practice is organizational behavior that reflects preoccupation with failure, reluctance to accept simplifications, sensitivity to operations, resilience to error and deference to experience. High-reliability organizations (HROs) have similarities to healthcare systems because they are confronted with myriad unexpected events under high stakes conditions—yet, unlike healthcare systems, HROs consistently achieve quality outcomes. Results are directly related to their capability for high-reliability practice: the ability to sustain steadfast attention to discriminatory detail and take decisive action amidst the weakest warning signals of error potential.[91]

Characteristics of a high-reliability health organization (HRO) include an organizational commitment to safety, back-up steps built into processes, safety measures and an organizational culture for continuous learning. The view is presented that there is growing evidence that applying reliability principles to health care has the potential to help reduce flaws in care processes, increase the consistency with which appropriate care is delivered and improve patient outcomes.[92]

Reliability is defined as failure-free operation over time. In health care, this definition connects to several of the IOM's aims for the health care system, particularly effectiveness (where failure can result from not applying evidence), timeliness (where failure results from not taking action in the required time), and patient-centeredness (where failure results from not complying with patients' values and preferences).[88] A HRO provides safe care and is intentionally designed to minimize errors while achieving exceptional performance in quality and safety. Reliability is defined as defect-free operations and a HRO is one that functions in a hazardous environment, yet is essentially error-free for long periods of time.[92]

The Institute for Healthcare Improvement (IHI) uses a three-step model for applying principles of reliability to health care systems:[88]

- Prevent failure (a breakdown in operations or functions)
- Identify and mitigate failure: Identify failure when it occurs and intercede before harm is caused, or mitigate the harm caused by failures that are not detected and intercepted.
- Redesign the process based on the critical failures identified.

Within each step of this model, specific reliability principles and change concepts can be applied to reduce ambiguities and opportunities for error, and improve the reliability of the processes used to support care.[88]

A proposed High Reliability Framework in Hospitals was described as having three major domains including 14 essential components:[93]

- Leadership: Board, CEO/Management, physicians, quality strategy, quality measures, information technology
- Safety culture: trust, accountability, identifying unsafe conditions, strengthening systems, assessment
- Robust process improvement: methods, training, spread; could be achieved through quality improvement models such as Six Sigma, Lean and/or change management

Members of high-reliability teams (HRTs) exhibit four key behaviours: situational awareness, use of standardized communication, closed-loop communication and shared mental model. High reliability requires not only knowing how to use these individual skills but also requires the practitioner to know & when to use them.[92]

5.4.1 Patient-Focused High Reliability Team Training (PHReTT)

Principles of high-reliability practice, human factors, CRM, military team training, and healthcare quality were synthesized to create Patient-focused High Reliability Team Training (PHReTT) for the purpose of teaching frontline nurses how to improve patient safety. The principal goal of the healthcare component of PHReTT is to develop specific individual and team high-reliability nursing practice competencies through training in team adaptation and coordination, team self-correction, and stress inoculation. Team adaptation and coordination training allows participants to apply explicit healthcare safety-oriented, teamwork communication skills, whereas self-correction trains participants in learning to create a shared mental model for improved performance. PHReTT teaches nurses how to improve patient safety at the front line of care. By learning high-reliability behaviors and how to evaluate these behaviors in practice, nurses in frontline leadership positions have the greatest potential to affect patient outcomes.[91]

5.4.2 Deep Stage High Reliability

High hazard organizations have been found to follow a typical developmental sequence in which they start with a local and decentralized knowledge structure and then move toward a more formalized and standardized design best suited to establishing control. The 'control' form can be highly attractive to managers, engineers, regulators, and others who desire reliability and safety. However, since everything cannot be anticipated and controlled, organizations that have stalled in their improvement efforts attempt to open their boundaries (for example, try to learn from other organizations) and achieve increased flexibility and innovation. This is often, although not always, at odds with practices and beliefs around control. If organizations can move beyond openness to a deep and systemic understanding of their operations, they stand a better chance of sustaining the structures and culture that can integrate or maintain productive tension between control and flexibility or learning.[90]

Deep Stage High Reliability design is achieved when an organization links positive aspects of the local, control and open stages to systems thinking. Systems thinking is a discipline and framework that helps organizations to perceive interrelationships underlying situations or events and to identify short and long term patterns of change rather than static "snapshots". Reliability in complex organizations such as hospitals, healthcare systems and multiple provider practices can be enhanced by moving towards the deep stage. To improve their reliability, healthcare organizations will need to tolerate and manage the tension between formal bureaucratic controls and continual improvisational adjustments. An appropriate "balance" or compromise among the many control and innovation mechanisms is a step towards an integrated approach based on deep system knowledge.[90]

5.5 Staff Training and Teamwork

5.5.1 Crew Resource Management (CRM)

In the aviation industry, Crew Resource Management (CRM) has aimed to improve flight safety by focusing on teamwork to prevent and manage crew-based errors. Three tiers by which CRM defends against errors are: avoidance of error, "trapping" of errors before they are committed, and mitigation of the consequences of those errors that are not trapped.[78]

In Response to the IOM 1999 report, the Quality Interagency Coordination Task Force recommended that a means to improve patient safety was to improve the underlying teamwork dynamics within the health care industry. This task force called for increased emphasis on the use of CRM training programs within health care. As a result of these recommendations, the use of CRM initiatives within the health care industry has become increasingly popular within the last several years.[84]

A Crew Resource Management approach enhances work relationships through a structured approach to staff working in the complex health care environment. Like a crew in an airplane cockpit, roles, responsibilities, and protocols are systematized and not dependent on the individual serving in that role.[82]

5.5.2 Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS)

The U.S. Congress commissioned the Department of Defense and the Agency for Healthcare Research and Quality (AHRQ) to translate the principles of a Just Culture into a format applicable to the delivery of healthcare. The result of this collaboration was the TeamSTEPPS (Strategies and Tools to Enhance Performance and Patient Safety) approach to patient safety.[24]

TeamSTEPPS is an evidence-based teamwork system aimed at optimizing patient outcomes by improving communication and other teamwork skills among healthcare professionals.[91] It focuses on leadership and communication skills (with scripting), mutual support of team members, and situation monitoring. It identifies barriers, suggests observation tools, and focuses on outcomes. TeamSTEPPS also helps participants assess whether

the Safety Culture is being sustained. The goal of TeamSTEPPS is the establishment, nurturing, and preservation of a Just Culture in which 'we immediately speak up when we think we see an unsafe practice developing'.[24]

5.6 Risk Management and Error Prevention

5.6.1 Four Essentials Bow Tie

The Four Essentials Bow Tie model uses four 'Essentials' as the main prevention barrier for problems or threats occurring in four major areas of company business namely: Organization, Supply Risks, Processes and Employees.[93]

The 'Four Essentials' are:[93]

- E1 – Keep it Simple System Structures (KiSSS): Systems may be complex but their structures must be simple to be easily understood by everyone
- E2 – Classification of Systems and Components (Risk Allocation): Importance levels are assigned to product and service systems and components for closer monitoring, better resource allocation and effective risk management.
- E3 – Special Process Qualifications (4M Process Variables): The 4Ms (Manpower, Method, Material and Machines) resources are approved prior to regular use to ensure these processes are kept in control.
- E4 – Competent and Happy People (Human Factors): These are crucial for achieving company goals and guarding the company's quality reputation.

While the Bow Tie model is seen as primarily a risk and safety analysis tool originally developed for use in North Sea oil projects, it can be adapted for any situation causing sub-optimal process control. The 4E Barriers to loss of system control and the appropriate mitigation or recovery measures to limit undesirable consequences provide the basis for companies to analyse their processes. The 4E Bow Tie can be used to address the common factors limiting business success such as:[93]

- Staff have trouble seeing the 'big picture'
- Communication across the company is poor
- Data and information flow is inadequate
- Operational risks are not properly identified
- Process controls are not always effective
- Stress levels and error rates are high
- No time to deal with systemic problems

The 4E Bow Tie model is presented as simple system model which can incorporate the most complex of risk assessment tools including QRA Fault Tree and Event Tree techniques as well as HF analysis and process design, which are crucial for maintaining process control. The fundamental purpose of the model is to develop business systems with failure prevention mechanisms, including reduction of human error to increase the probability of overall business success.[93]

5.6.2 Poke Yoke

Poke yoke (poh-kah yoh-kay) is a Japanese term and approach, the purpose of which is mistake-proofing a design or process, originally applied to the manufacturing industry by Shiegeo Shingo of Toyota. The underlying concept of poke yoke is that defects occur because of worker errors. Therefore, to prevent errors, a mechanism needs to be in place to alert the worker to the potential for error and, where possible, eliminate the error early in the process thereby taking a preventive approach. Although poke yokes may be used for mistake-proofing any process, poke yokes are usually targeted to repetitive tasks where the potential for human error is more likely.[37]

5.6.3 Clinical Risk Management

Clinical risk management has been defined as "an approach to improving quality in healthcare which places special emphasis on identifying circumstances which put patients at risk of harm, and then acting to prevent or control those risks. The aim is to both improve safety and quality of care for patients and to reduce the costs of such risks for health care providers". From a more practical point of view, it has been defined as "the system of guidelines, protocols, steps, organizational and clinical procedures adopted by a hospital to reduce the probability that events and actions, that might potentially produce negative or unexpected effects on the health of patients, occur".[96]

Clinical risk management offers a possible avenue of approach for human factors specialists, as it is an approach to quality and safety which specifically targets adverse events and is modelled on risk management approaches in other settings.[23]

5.6.4 Hazard Analysis Critical Control Points (HACCP)

Hazard Analysis Critical Control Points (HACCP) is a process which focuses control at those points in a process which are critical to the safety of the end product. The hazard analysis critical control points (HACCP) concept evolved from team work by Pillsbury, National Aeronautics and Space Agency (NASA) Natick Laboratories of the US Army and US Air Force Space Laboratory Project Group. It was originally designed to guarantee that the food provided for space travellers was not contaminated microbially, chemically, or physically, in a way that would lead to either a space mission failure or catastrophe.[97]

The HACCP approach was used in an ophthalmology unit when conventional infection control measures had failed to solve an ongoing problem with an increased incidence of infection and permanent cessation of intraocular surgery was threatened. Although time-consuming, the result was an entirely new set of protocols for the care of patients undergoing intraocular surgery, the development of an integrated care pathway, and a comprehensive and robust audit programme, which enabled intraocular surgery to continue in a new spirit of confidence. HACCP methodology has so far been little used in healthcare, but it might be usefully applied to a variety of apparently intractable infection control problems. The protocols developed formed the basis of a multidisciplinary integrated care pathway which would have been more difficult to achieve in the absence of prior analysis by HACCP methodology.[97]

5.6.5 Shell Model

The SHELL Model is a conceptual tool used to analyze the interaction of multiple system components including humans. The Shell Model contains the following four components:[5]

a) Software (S): procedures, training, support, etc.;
b) Hardware (H): machines and equipment;
c) Environment (E): the working environment in which the rest of the L-H-S system must function; and
d) Liveware (L): humans in the workplace.

The SHELL Model is useful in visualizing the following interfaces between the various components of the aviation system:[5]

a) Liveware-Hardware (L-H): The L-H interface refers to the relationship between the human and the physical attributes of equipment, machines and facilities; human performance in the context of aviation operations, natural human tendency to adapt to L-H mismatches.
b) Liveware-Software (L-S): The L-S interface is the relationship between the human and the supporting systems found in the workplace, eg regulations, manuals, checklists, publications, standard operating procedures (SOPs) and computer software.

c) Liveware-Liveware (L-L): The L-L interface is the relationship among persons in the work environment. It is important to recognize that communication and interpersonal skills, as well as group dynamics, play a role in determining human performance. The advent of crew resource management (CRM) and its extension to air traffic services (ATS) and maintenance operations has created a focus on the management of operational errors across multiple aviation domains. Staff/management relationships as well as overall organizational culture are also within the scope of this interface.
d) Liveware-Environment (L-E): This interface involves the relationship between the human and both the internal and external environments. The internal workplace environment includes such physical considerations as temperature, ambient light, noise, vibration and air quality. The external environment includes operational aspects such as weather factors, aviation infrastructure and terrain. Psychological and physiological forces, including illness, fatigue, financial uncertainties, and relationship and career concerns, can be either induced by the L-E interaction or originate from external secondary sources.

According to the SHELL Model, a mismatch between the Liveware and the other four components contributes to human error. Thus, these interactions must be assessed and considered in all sectors of the aviation system.[5]

5.6.6 Sensitizing Model for Safety Assessment

The necessity of moving beyond traditional methods and tools designed for assessing safety has been recognized. So far, methods have been dominated by technologically and quantitatively oriented rationales (eg probabilistic safety assessment), with attempts to complement them from other backgrounds such as human factors (eg human reliability assessment). The current and next generation of technological developments require enhanced abilities, both from states, public and private companies, to better anticipate technological, human, organizational and socio-cultural types of failures. This will require better interface between technology and social sciences and their translation into safety assessment practices.[98]

A sensitising model has been presented which aims to provide a perspective to improving safety assessment beyond a technologically oriented approach unable to incorporate the dynamical and systemic side of safety. This sensitising model incorporates knowledge from the social sciences. It addresses the theoretical problems including that data collection and interpretation are always, whether implicitly or explicitly, to a large extent knowledge-driven. The model attempts to qualitatively include the dynamic interplay between technological design and tasks, structural and functional features of organizations, but also the cognitive, cultural and power issues at several nested layers of analysis. It indicates the dimensions that need to be considered. The sensitizing model has predictive ambitions, is forward- looking, not backward-looking. It searches for key dynamical features of systems that must be understood to assess trends or patterns likely to produce unwanted events in high risk systems.[98]

5.7 System-Theoretic Accident Model and Processes (STAMP)

System-Theoretic Accident Model and Processes (STAMP) is based on the hypothesis that accidents can be analyzed through system theory.[99] An argument has been presented that sophisticated models of causality based on systems thinking and systems theory presents an opportunity to perform more powerful accident analysis and hence learning from events. STAMP is a model of causality which places increased emphasis on proactive analysis.[100]

In the STAMP conception of safety, accidents occur when external disturbances, component failures, or dysfunctional interactions among system components are not adequately handled by the control system. Accidents result from inadequate control or enforcement of safety-related constraints on the development, design, and operation of the system. Based on this premise, safety then is viewed as a control problem and is managed by a control structure embedded in an adaptive socio-technical system. The control structure's role is to

enforce constraints on system development and system operation that result in safe behavior. Understanding why an accident occurred requires determining why the control structure was ineffective. Preventing future accidents requires designing a control structure that will enforce the necessary constraints. STAMP focuses particular attention on the role of constraints in safety management. Instead of defining safety in terms of preventing component failure events, it is defined as a continuous control task to impose the constraints necessary to limit system behavior to safe changes and adaptations.[99]

5.8 Incident Reporting

5.8.1 Aviation Model of Incident Reporting and Investigation: Aviation Safety Reporting System (ASRS) and Aviation Safety Action Program (ASAP)

In the aviation industry, reporting of near misses and adverse events is an important source of data regarding errors. Proponents of an incident reporting system for surgery have suggested using the Aviation Safety Reporting System (ASRS) and the Aviation Safety Action Program (ASAP) as models. The ASRS allows for voluntary, non-punitive, anonymous (both the airline and the individual) reporting of incidents. Similarly, ASAP allows for airline-based incident reporting that supports corrective actions. It is reported that, in surgery, errors but not near misses are reported in morbidity and mortality conference. However, reporting of adverse events is not anonymous and not always without recrimination. Furthermore, in surgical morbidity and mortality conference, errors are not always admitted (24% of cases) or explicitly discussed (40%). Even complications and deaths may be underreported when compared with other methods of surveillance. As well, morbidity and mortality conference does not include a standardized mechanism for feedback to the healthcare system.[73]

Reporting systems must be viewed as more than simple counting systems and systems that identify the negative events, rather they must identify the vulnerabilities in our health-care system and trigger appropriate systems-based action. To be successful, safety reporting systems need to be non-punitive, as well as perceived that way. This means that the information contained in them cannot result in the punishment of an individual. To accomplish this, the safety reporting system must de-identify its data. Names, as well as any information that could be used to infer the identity of individuals, need to be excluded. This approach demonstrates that the organization is committed to moving from the 'train and blame' approach to a systems-based approach. Such a change will boost the confidence of individuals that their reports will be used in a productive manner and that they have little reason to fear and make them more likely to report problems.[89]

The type of information reported is also a consideration. Bad-outcome events will always be included. However, from the aviation experience as well as the health-care experience, it is clear so-called 'close calls' are an essential and rich source of information. Learning can occur even when no one is harmed. Most organizations do not incorporate such learning as a standard operating procedure. This is considered to be short sighted, as the organization that ignores lessons from close calls is essentially declaring that they will wait for a tragedy to occur before making changes.[89]

An aviation model of incident reporting and investigation was implemented in the Department of Neurosurgery. After specific training in safety culture, the authors implemented an aviation-derived prototype of incident reporting. They then developed an experimental protocol to track, analyze, and categorize any near misses that happened in the operating room.[101]

5.9 Safety-II and Resilience Engineering

The thinking underlying Safety-II is that safety management should move from ensuring that 'as few things as possible go wrong' to ensuring that 'as many things as possible go right'. According to Safety-II, the everyday performance variability needed to respond to varying conditions is the reason why things go right. Humans are

consequently seen as a resource necessary for system flexibility and resilience. The safety management principle is continuously to anticipate developments and events. The purpose of an investigation changes to understanding how things usually go right as a basis for explaining how things occasionally go wrong.[102]

During the second half of the 20th century the technical environment changed and the focus of attention shifted from technological problems to human factors problems and finally to problems with organizations and safety culture. The view is expressed that, unfortunately, most of the models actually used to analyse and explain accidents and failures did not develop in a similar way. The result is that safety thinking and safety practices in many ways have reached an impasse. This was the primary driver for the development of resilience engineering in the first decade of this century.[102]

Resilience engineering acknowledges that the world has become more complex, and that explanations of unwanted outcomes of system performance therefore no longer can be limited to an understanding of cause-effect relations described by linear models. Instead of only looking at the one case in 10,000 where things go wrong, the 9,999 cases where things go right should be studied. Things go right because people are able to adjust their work to the conditions. Safety-II is the system's ability to succeed under varying conditions, so that the number of intended and acceptable outcomes is as high as possible. A system is said to be 'resilient' if it can adjust its functioning prior to, during, or following changes and disturbances, and thereby sustain required operations under both expected and unexpected conditions.[102]

6.0 Quality Management Tools

In the process of this literature review, many 'tools', techniques or methodologies used in quality and safety management were found. Descriptions regarding how quality and safety tools such as IDEA model, FMEA, walkrounds, etc. were implemented in hospitals were also found in the literature.[103]

Some interesting tools and techniques follow.

6.1 Logical Framework Analysis (LFA) or Logframe

Logical framework analysis (LFA) is a matrix approach to project planning for managing quality. It provides an integrated approach which can identify and analyze issues, provide solutions to resolve those issues, develop a project management framework (planning, monitoring, and evaluating) to implement those solutions in order to improve process performance. This integrated and uniform quality management tool integrates operations with organizational strategies.[104,105]

A Logical Framework is an analytical management tool that helps to:[106]

- Analyze existing situations during project preparation;
- Establish a logical hierarchy by which objectives will be reached;
- Identify potential risks to achieving objectives and to sustainable outcomes;
- Establish how outputs and outcomes might best be monitored and evaluated;
- Present a project summary in a standard format; and
- Monitor and review projects during implementation.
- Communicate project information.
- Make decisions across various phases of project.
- Evaluate project after completion.

The approach involves problem analysis, stakeholder analysis, developing hierarchical objectives and selecting a preferred implementation strategy. The product is a matrix (the logframe), which summarizes the project's intentions and modus operandi.[106]

The product of this analytical approach is the matrix (the Logframe), which summarizes the intentions and modus operandi of the project, its key assumptions and the methods of monitoring and evaluating outputs and outcomes. The logical framework considers all the three quality measures (structure, process, and outcome) of healthcare delivery. It also facilitates monitoring and evaluation of implementation dynamically for continuous quality improvement (CQI) of processes. A logical framework offers a uniform and integrated model, which can be applied to most of the healthcare units covering both clinical and non-clinical departments. The model establishes a link between organizational learning, resource-based theory and strategic management. LFA is not the replacement of the conventional quality management practices but a supplement to these with structured planning, implementation and evaluation framework.[104,105]

6.2 SERVQUAL

SERVQUAL is a standard instrument for measuring functional service quality, presented as being reliable and valid in the hospital environment and in a variety of other service industries. It will enable researchers to test the effectiveness of quality-enhancing techniques and actions across a range of industries and to develop generalizations about these actions and methods.[53]

SERVQUAL contains five service dimensions: tangibles, reliability, responsiveness, assurance and empathy:[53]

- Tangibility includes physical facilities, tools, or equipment and appearance of personnel
- Reliability is the ability to perform the expected service dependably and accurately
- Responsiveness means the willingness to provide prompt service and help customers
- Assurance is courtesy and knowledge of service providers and their ability to inspire and build confidence
- Empathy is the providing of caring and individual attention to customers.

6.3 Evaluation and Quality Improvement Program (EQuIP)

The Evaluation and Quality Improvement Program (EQuIP) provides a management framework to facilitate integration of quality improvement strategies into the normal business of the organization. EQuIP can be used as the tool that operationalizes the hospital's quality directions, such as an approach to business of all staff having the shared goal of providing the best possible care to patients within a framework of shared values, strategic and systems thinking that demolishes the usual professional and departmental boundaries. EQuIP provides a framework within which to plan an integrated learning environment necessary to consistently achieve high quality outcomes.[107]

6.4 Benchmarking

Benchmarking is the value of selected parameters used as a reference point to compare the effectiveness of various processes within one corporation with another, the information obtained then used to improve processes. Benchmarking is a part of total quality management and has become a competitive technology in many successful companies.

The benchmarking process is composed of four phases: planning, analysis, integration and action phases. Planning involves the complete understanding of the existing internal processes and measurements. The analysis phase involves analyzing the benchmarking data to identify and understand the practices which best contribute to the subject's strengths. In the integration phase, the company develops goals and integrates them into the benchmarking process to obtain significant performance improvements. The action needed to achieve the goal is decided in the integration phase.[108]

6.4.1 Quality Benchmarking Deployment (QBD)

The Quality Benchmarking Deployment (QBD) methodology has been developed to accomplish the task of measuring the gap between the company's products and those of the best company in the industry based on the technique of 'house of quality', The 'house of quality' is used to organize the qualitative and quantitative data that is gathered and to identify an organization's competitive benchmarking. The QBD puts emphasis on the competitor's analysis and reveals the company's position with respect to competitors. The house of quality consists of four main parts: customer needs, design attributes, relationship matrix and competitive benchmarking. QBD helps management compare their products and services with the best in the industry.[108]

6.5 Balanced Scorecard (BSC)

The Balanced Scorecard (BSC) provides a medium for translating a vision into a clear set of objectives which are then further translated into a system of performance measurements that effectively communicate a forward looking, strategic focus on the entire organization.[72]

The Balanced Scorecard (BSC) approach avoids excessive emphasis on financial measures and tries to achieve a balance among customer perspectives, learning and growth, internal business processes and financial measures.[109] The BSC has been implemented at the corporate, strategic business unit, departmental, shared-service and individual levels by hundreds of organizations worldwide, including the business and healthcare sectors and by both private and public enterprises. By emphasizing the importance of customer perspective to performance, the BSC significantly influences the progress of organizations in pursuing quality.[109]

6.6 Team Performance Measurement Model

The Team Performance Measurement Model provides feedback for continuous improvement to teams in a total quality system. It helps teams to diagnose problems with all critical elements of their work, including the team structure, inputs, processes and outputs. Through application of this model, management receives comprehensive and easy to understand information about the general progress of their teams. The model helps management to determine which teams need more support in which areas and can develop more effective strategies and actions to help teams succeed.[110]

The Team Performance Measurement Model has four components: team structure, inputs, processes, and outputs. It suggests methods for developing measures in each component, and use of radar charts for presenting measurement results. Teams work together to develop the measures and necessary data collection mechanisms. Management validates the appropriateness of the measurement systems developed with regard to organizational policies, goals and objectives.[110]

6.7 Enterprise Resource Planning (ERP)

Enterprise Resource Planning (ERP) is an integration of business management practices and modern technology. ERP is an integrated computer-based system used to manage internal and external resources including tangible assets, financial resources, materials, and human resources. It is a software architecture whose purpose is to facilitate the flow of information between all business functions inside the boundaries of the organization and manage the connections to outside stakeholders. ERP's key objective is to integrate information and processes from all functional divisions of an organization and merge it for effortless access and structured workflow.[8]

6.8 Pay for Performance (P4P)

The concept of pay for performance (P4P) has gained traction in recent years to link payments to quality performance. The quality measures required by payers may include readmission rates, hospital-acquired infection rates, mortality rates for select conditions, and patients' satisfaction. More than one hundred provider

organizations in the US have already worked with private health plans using the accountable care organization (ACO) model with 'payment tied to improving patient's care across the continuum and reducing overall spending growth'.[47]

6.9 Quality Broom

The Quality Broom is introduced as a metaphor for different management approaches required to respond to the different kinds of processes in healthcare. A broom is made out of three components: a hard unyielding stick, a soft flexible part made of a bundle of straws and a connector between these. The stick provides rigidity and the straws flexibility and tenacity. Applying this image to an organization, the broomstick represents repetitive, standardized operations where each step in terms of inputs, conditions and activities is identical or close to identical, and outcomes are known with reasonable certainty. The bundle of straws represents non-routine systems with a variety of flexible movements. The connector represents routines where rigidity and flexibility are brought together. The managerial implication of the broom-metaphor is to determine where various processes and activities are located in terms of uncertainty and thereby to what extent they may be standardized, routinized or left to empowered local experts. The broomstick can be managed with quality systems and standards while the most viable way to impact on the flexible part of the organization is through organizational culture, the creation of professional pride.[111]

7.0 Safety Management Tools

7.1 Root Cause Analysis (RCA)

Root Cause Analysis (RCA) is a term used to describe a structured methodology for the retrospective investigation of adverse incidents, near misses and sentinel events, originally developed to analyse major industrial incidents. The quality and efficacy of the process relies on consistent and meticulous incident reporting and analysis.[112]

The aim of Root Cause Analysis is to determine the etiology of adverse incidents that lead to patient harm and produce a series of recommendations, which would minimise the risk of recurrence of similar events, if appropriately applied to clinical practice. Literature defines root cause as the element that, if corrected, would prevent similar incidents from happening and assists in determining a management plan should the same or a similar incident occur.[112]

Reference to RCA is found in the reliability literature related to avoidance of future occurrence of failures by pinpointing the causes of problems. It provides comprehensive classification of causes related to 4Ms: ie man, machine, materials and methods, and thus helps in establishing a knowledge base to deal with problems related to process/product reliability, availability and maintainability.[113]

A critical component of an environment that supports patient safety is routine RCA of adverse events, including answering the three questions: What happened? Why? What can be done to prevent it in the future? RCA assists in identifying systems problems that contribute to the adverse event.[82]

One hospital implemented an IDEA model - identify a problem, determine its root cause, evaluate prospective interventions and act - as its quality road map.[103]

7.2 Failure Mode Effects Analysis (FMEA)

Failure Mode Effects Analysis (FMEA) is a tool used by system safety and reliability engineers to identify critical components/parts/functions whose failure will lead to undesirable outcomes such as production loss, injury or even an accident. First proposed by NASA in 1963, it been extensively used as a technique for system safety and

reliability analysis of products and processes in a wide range of industries – particularly aerospace, nuclear, automotive and medical.[113]

One of the hallmarks of a safe organization is that it consistently and routinely monitors its own environment to assess what could go wrong. A safe organization is characterized by a preoccupation with failure, great systems to identify failures and potential weaknesses, and the ability to address them. FMEA is a systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change.[82]

FMEA is often initiated by a "near-miss" or concern for risk as opposed to a root cause analysis that is initiated solely after a sentinel event. It is presented as an effective tool to assess and prioritize areas of risk in clinical practice. In contrast to a root cause analysis, the FMEA looks more broadly at processes involved in the delivery of care.[114]

FMEA includes review of the following:[115]

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?)

Teams use FMEA to evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting to adverse events after failures have occurred. This emphasis on prevention may reduce risk of harm to both patients and staff. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.[115]

While FMEA originated as an engineering tool used in industry, it is also used by health care organizations to test patient safety systems. In this setting, failure mode analysis takes a hypothetical patient through a continuum of care with the assumption that something goes wrong at every step and that each safety net fails.[116]

Steps in performing an FMEA:[117]

- Identify the intended objective or purpose of each process step:
- Identify the potential failure modes for each process step:
- Identify the causes of each potential failure mode
- Identify the local, downstream, and end effects of the failure mode.
- Identify all of the process controls currently in place that achieve the following:
    - Prevent the causes of failure modes from occurring.
    - Detect failure modes when they do occur.
    - Mitigate the severity of the effects resulting in failure modes when they do occur.
- Judge the effectiveness of the current process controls, using three independent ranking scales, with each scale being from 1 to 10.
- Complete the scoring.
- Identify recommended actions (process controls) that will reduce the risk of injury.
- Estimate new occurrence, severity, and detection scores for the process after implementing the recommended actions and calculate the resulting Risk Priority Number (RPN).
- The last step in completing an FMEA is to identify the individuals responsible for implementing the recommended actions that will improve the process controls; a completion date also should be entered.

7.3 Trigger Tool for Adverse Events

Performance improvement programs have traditionally focused on the voluntary reporting of errors. However, because it is stated that fewer than 20% of errors are reported, and because up to 95% of reported errors caused no patient harm, the focus has now shifted to recording sentinel alerts that indicate potential patient safety risks.[115]

Identifying "triggers" of adverse events during a manual chart review has been used extensively to measure the overall level of harm in a health care organization. The IHI developed the Global Trigger Tool for Measuring Adverse Events, intended to be used to identify all categories of adverse events including, but not limited to, those related to medications.[82] It was designed to identify sentinel events or laboratory values without reliance on voluntary reporting and to maximize the benefit of chart audits with small sample sizes.[116]

A disadvantage is that the method requires a review of all adverse events (AEs) that meet trigger definitions, whether the events were preventable or not. In large organizations, the system allows continuous real-time monitoring of electronic health records to identify potential patient safety issues.[116]

7.4 Human Error Modes and Effects Analysis (HEMEA)

A human hazard analysis methodology is a tool for managing human error in aircraft maintenance, operations and production. The methodology takes traditional aspects of the aircraft design system safety process, particularly fault tree analysis, and couples them with a structured tabular notation called a human error modes and effects analysis (HEMEA). HEMEA provides data, obtained from domain knowledge, in-service experience and known error modes, about likely human-factors events that could cause critical failure modes identified in the fault tree analysis. In essence the fault tree identifies the failure modes, while the HEMEA shows what kind of human-factors events could trigger the relevant failure. Effectiveness of the methodology is dependent on obtaining the relevant expert judgement and domain knowledge.[118]

7.5 Fault Tree Analysis (FTA)

Fault Tree Analysis (FTA) is an analytical technique used for reliability, maintainability and safety analysis. FTA attempts to integrate all factors affecting the success or failure of a product, process or mission into a single FTA Logic Diagram. The FTA Logic Diagram provides a method for defining the complex relationship existing between the hardware, software and human components of a system. FTA is performed by systematically determining what happens to the system when the status of a part or element of the system is changed.[119]

7.6 Advanced Incident Management System (AIMS)

The Advanced Incident Management System (AIMS) is an integrated incident reporting and management system currently in use across the universal public health system in five of the eight states and territories of Australia, with additional sites in other states and in New Zealand, and a pilot site in the USA. The system provides software to facilitate entering of basic data and classification into a customisable form, notification of relevant people and recommendation for local action. Risk assessment is presented as a score in a matrix based on severity and likelihood of recurrence. If the risk is low and the incident is of local relevance only, this may be all that needs to be done. However, if the risk is high or someone has been harmed, a patient safety officer or line manager may decide to elicit more information and classify the incident in detail.[120]

7.7 Quality and Safety by Design

A three level conceptual framework design using the six quality aims laid out in 'Crossing the Quality Chasm' is proposed to be used to design quality and safety into health systems. The premise is that, rather than continuing to try to measure the width and depths of the quality chasm, one should begin to close the quality chasm. One way

to think about the problem is as a design challenge rather than as a quality improvement challenge, to move from reactive measurement to proactive use of proven design methods, and to involve a number of professions outside health care to design out system failure and design in quality of care. The first or core level of the framework would be designing for patient centered care. Safety would be the second level. The third level would include design attributes of efficiency, effectiveness, timeliness, and equity. Design methods and approaches are said to be available that can be used for the design of healthcare organizations and facilities, learning systems to train and maintain competency of health professionals, clinical systems, clinical work, and information technology systems. In order to bring about major improvements in quality and safety, these design methods can and should be used to redesign healthcare delivery systems.[121]

7.8 Simulation

Simulation is used to teach people to recognize problems and understand the effects of their responses. It has been used effectively in many industries, particularly in aviation. The technique is particularly helpful in preparing people for error-prone, high-risk, or unusual situations. Simulations can be as simple as practicing wheeling a patient bed from one patient care unit to the ICU, and as complicated as visiting a dedicated patient safety lab used as a simulation theater. Simulation addresses not only the technical performance of individuals, but also important elements of teamwork such as listening, communicating, respect, and role clarity. Knowing how to conduct simulations is an important staff competency. Simulation has many applications in health care; an organization's investment of staff time in simulation or in a patient safety laboratory demonstrates the leadership's commitment to a safety culture.[82]

7.9 Human Factors Approach and Human Factors Analysis & Classification System (HFACS)

The Human Factors Approach focuses on behaviors that contribute to safe and efficient performance, including situation awareness, decision making, leadership and teamwork. The approach has been used in aviation and is now being adopted by other industries, including healthcare.[76]

Health care quality improvement goals have emphasized increased use of human factors engineering and systems engineering principles in addressing the prevalence of adverse events and misadministration in health care settings. Since the early 1990's, applying human factors principles to medical systems has been a growing trend as a means to reduce the prevalence of human performance-related errors and adverse outcomes in healthcare. Human behavior that enhances system performance and a range of factors affecting adverse events have been studied, rather than a sole emphasis on human error causation.[122]

Studies have begun to address the complexity of the relationship between human behaviour and technology, tasks, environment and organization. Human factors frameworks have been usefully applied that aid in these complex considerations, providing a better understanding of the healthcare system, and a broader range of solutions to problems than checklists, protocols or training.[123] The importance and role of human factors in quality management in production enterprises, particularly on quality in stages of design, production, and exploitation of products has been recognized. Humans create, produce, and use the quality of products according to their needs, goals, and value systems.[2]

The Human Factors Analysis and Classification System (HFACS) serves as an error framework based on Reason's model of latent (at the system level or 'blunt' end) and active (at the frontline or 'sharp' end) errors. When failures align across multiple levels, an accident trajectory is created, resulting in an adverse event. Human factors analysis has also been used to examine an activity in terms of its components such as technical and nontechnical skill demands, mental workload, interactions with technology and the work environment, and team dynamics. Using

this framework for identifying and classifying errors may allow for a better understanding of why near misses and errors occur so as to develop preventative strategies.[78]

The Human Factors Analysis and Classification System (HFACS) describes four levels of failure as:[124]

- Unsafe acts (of operators).
- Preconditions for unsafe acts.
- Unsafe supervision.
- Organizational influences.

HFACS is a model that can be transposed to help illustrate the origins of error in healthcare and can also be used in retrospective investigations of healthcare errors.[124]

7.10 Safety Attitudes Questionnaire (SAQ)

The Safety Attitudes Questionnaire (SAQ) was adapted from the Flight Management Attitudes Questionnaire (FMAQ) for use in healthcare. The 23 item questionnaire utilizes a five-point scale to evaluate six key factors: teamwork climate, job satisfaction, perceptions of management, safety climate, working conditions, and stress recognition. The SAQ has been formally evaluated with pilot testing and confirmatory factor analyses and has been modified for use in different healthcare arenas including intensive care units, labor and delivery units, operating rooms, general inpatient and ambulatory settings. Based on extensive testing across three countries, 203 clinical areas, and over 10,000 health care providers, the SAQ has been psychometrically validated for use in the medical field.[78]

A recent review of safety climate instruments in health care highlighted the SAQ as the leading instrument because it meets 22 of 23 essential criteria (eg, content, validity, and reliability). The safety climate scale is valid, sensitive to interventions, and the attitudes elicited associated with patient length of stay and error rates. Safety climate scores were found to vary widely among patient care areas within a given hospital; therefore, safety climate was assessed at the patient care area level rather than the hospital level.[84]

7.11 Line Operations Safety Audit (LOSA)

Line Operations Safety Audit (LOSA) is a proactive safety data collection program. Data generated through the program provide a diagnostic snapshot of organizational strengths and weaknesses, and an assessment of flight crew performance in normal flight operations. The business principle of measure, implement change and measure again is applied, with metrics of effectiveness being provided by LOSA. LOSA is an organizational tool used to identify threats to aviation safety, minimize the risks such threats may generate and implement measures to manage human error in operational contexts. Operators are enabled to assess their level of resilience to systemic threats, operational risks and front-line personnel errors, thus providing a principled, data-driven approach to prioritize and implement actions to enhance safety. LOSA uses expert and highly trained observers to collect data about flight crew behaviour and situational factors on "normal" flights. Strict no-jeopardy conditions are maintained during the audits so that flight crews are not held accountable for their actions and errors that are observed. During flights that are being audited, observers record and code potential threats to safety; how the threats are addressed; the errors such threats generate; how flight crews manage these errors; and specific behaviours that have been known to be associated with accidents and incidents. LOSA is closely linked with Crew Resource Management (CRM) training. Data from LOSA also provide a real-time picture of system operations that can guide organizational strategies in regard to safety, training and operations.[125]

7.11.1 Behavioral Markers

Behavioral markers have been measured in aviation using tools such as the Line Operations Safety Audit (LOSA). They are observed behaviors that have been correlated highly with team performance in context-specific, critical situations in high-risk industries. Markers associated with superior performance include assertiveness, leadership and situational awareness. Similar efforts have been made to characterize desired behaviors during medical crises, even using modifications of the LOSA, in the fields of neonatology, anesthesia, emergency medicine and surgery. However, the behaviors that are advantageous in a cockpit may not be the same as those required during surgery, and validity of these marker systems in the healthcare arena has not completely been demonstrated.[78]

7.12 Situation Awareness Global Assessment Technique (SAGAT)

Situation awareness refers to comprehension of what is going on and what is likely to happen next. Studies of situation awareness in aviation, using the Situation Awareness Global Assessment Technique (SAGAT), have been correlated to performance.[78]

Three levels of situation awareness have been identified in aviation:[78]

- Level 1 or perception of information from the current situation
- Level 2 or comprehension of the current situation, and
- Level 3 or projection of future events based on understanding of the current situation.

7.13 EDIT Model (Error Type, Direct Threat, Indirect Threat)

The EDIT model (Error type, Direct threat, and Indirect threat) enables the characterization of individual errors by evaluation of error type, performance-shaping factors (direct threats), and organizational factors (indirect threats), and is applicable to various hospital hazards. This model was further developed to prioritize organizational factors that underlie incidents in hospitals and to set a goal for safety improvements. Using this model, error analyses of a large number of incident reports enabled the construction of a database. The constructed database can envisage organizational factors in a fact-finding manner, which could not have been seen from analysis of individual incident reports.[126]

7.14 Theory of Inventive Problem Solving (TRIZ)

The Theory of Inventive Problem Solving (TRIZ; pronounced *trees*) is a systematic approach to stimulating innovation in design. It helps feed innovation by building on an empirical catalog of how technical innovation has occurred in the past. Process safety professionals encourage learning from events and accidents to avoid the same or similar event from recurring. Through TRIZ, inventive problem solving builds on the experience of thousands of previous problem solvers, and points to solution areas worthy of consideration. It is usually applied to objects and much less so to processes, chemical or otherwise.[37]

8.0 Overriding Considerations from the Literature

8.1 Governance, Management and Leadership

Management Philosophy is essential to successful implementation of safety and quality initiatives. A control-based management approach was found to be positively associated with culture of blame and negatively with learning from mistakes. In contrast, the commitment-based approach was negatively associated with Culture of Blame and positively with learning from mistakes, camaraderie, and motivation. Mediating variables of learning from mistakes and camaraderie showed a significant negative relationship with medical errors. Learning from mistakes, camaraderie, and motivation all showed a significant positive relationship with quality of patient care.[127]

It is proposed that the answer to further improvements in clinical outcomes does not lie in further investments in technology alone but also in improvements in the organization and management of health care delivery process. The management culture and systems in health care remain entrenched in the control-based model, which is consistent with the old industrial model of management. However, health care organizations are not factories. They are highly knowledge-intensive and service-oriented entities and thus require management culture and systems premised on the commitment of employees to achieving the highest level of quality of patient care. Health care organizations need to move away from controlling employees to involving them in decision making and providing them a just and fair work environment. Health care organizations need to break down silos that exist in their structures and embrace a management approach that encourages learning and camaraderie in the workforce.[127]

Seven **Leadership Leverage Points** were presented:[128]

- Establish and oversee specific system-level aims at the highest governance level
- Develop an executable strategy to achieve the system-level aims and oversee their execution at the highest governance level
- Channel leadership attention to system-level improvement: personal leadership, leadership systems and transparency
- Put patients and families on the improvement team
- Make the Chief Financial Officer a quality champion
- Engage physicians
- Build improvement capability

Clinical Governance represents the context in which effective clinical risk management should be promoted and continuously improved. The introduction of effective reporting systems is a cornerstone of safe practice within hospitals and other healthcare organizations. Reporting can help to identify hazards and risks. However, reporting in itself does not improve safety. It is the response to reports that leads to change. Clinical teams must feel empowered to change the way in which they deliver their services, promoting effective clinical risk management. Process analysis, implementation of evidence-based practices, and a clear accountability system are effective tools not only for decreasing error rates, but also for improving effectiveness. It should not be regarded as a separate activity, but should form part of the everyday practice of all healthcare professionals. Achieving a patient-centred and safer system requires good multidisciplinary working and a willingness to reflect on and learn from errors.[129]

8.2 Policy Levers for Change

The changing policy environment in the US healthcare system has implications for management of patient safety in healthcare. Three distinct mechanisms are proposed as being in use to prompt safer actions by hospitals:[130]

- Professionalism
- Regulation
- Markets

The national structure of the National Health Service in England may offer a greater ability to develop a multifaceted and coherent approach which marshals resources behind public policy goals and their implementation. The evolving policy environment in England offers new and different opportunities to improve safety. For example, harnessing the role of patient choice to drive and judge safety performance of providers is likely to become increasingly important. At the same time, the establishment of national standards for NHS care, of which safety forms a key component, will focus the attention of providers and commissioners on their performance in this domain. Deciding the best combination of policy levers is, to an extent, still experimental. For example, what is the right balance between external incentives such as regulation and inspection and an 'intrinsic' motivation to improve such as strengthening the professional ethos of clinicians? How is the current disconnection between professional concerns for patient safety at the level of the clinician-patient interface and the formal governance of clinical quality at the organizational level most effectively addressed? In addition, new levers such as financial incentives are being harnessed in the interests of patient safety. Empirical measurement of effectiveness is difficult given the close interrelationship between different interventions. It is stated that no single approach represents a complete response on its own.[130]

8.3 Culture

Several studies have described organizational cultures and explored associations between different cultural 'types' or 'attributes' and quality related outcomes. 'Cultural traits' such as the value placed on a commitment to public accountability, a willingness to work together and learn from each other, and the ability to be self-critical and learn from mistakes were associated with greater implementation of clinical governance in general practice. However, it is still unclear which set of shared beliefs and values is the most effective in fostering quality improvement.[131]

Don Berwick, when speaking about patient safety of healthcare in England in 2013, stated 'Culture will trump rules, standards, and control strategies every single time. A safer NHS will depend far more on major cultural change than on a new regulatory regime'.[132]

The Lucian Leape Institute, established by the National Patient Safety Foundation in the US, believes that healthcare entities must become 'high reliability organizations' that hold themselves accountable to consistently offer safe, effective, patient-centred care. This will require all parties including hospitals, boards, doctors, nurses, pharmacists, administrators, regulators, government officials, payers, professional societies and patients to move beyond the IOM recommendations for changes in systems and to radically change the ways in which they think about care and how it is provided. They contend that healthcare needs not just to be improved but to be transformed.[133]

With respect to culture in healthcare organizations, the Lucien Leape Institute envisions:[133]

- A culture that is open, transparent, supportive and committed to learning; where doctors, nurses and all health workers treat each other and their patients competently and with respect; where the patient's interest is always paramount; and where patients and families are fully engaged in their care.
- A culture centred on teamwork, grounded in mission and purpose, in which organizational managers and boards hold themselves accountable for safety and learning to improve. In a learning organization, every voice is heard and every worker is empowered to prevent system breakdowns and correct them when they occur.
- A culture that aspires to, strives for, and achieves unprecedented levels of safety, effectiveness, and satisfaction in healthcare.

To become safe, effective, high reliability organizations, healthcare organizations must implement five major transforming concepts:[133]

- Transparency must be a practiced value in everything that is done
- Care must be delivered by multidisciplinary teams working in integrated care platforms
- Patients must become full partners in all aspects of healthcare
- Healthcare workers need to find joy and meaning in their work
- Medical education must be redesigned to prepare new physicians to function in this new environment.

Each of these concepts calls for moving thinking beyond current boundaries and each implies profound behavioural changes.[133]

Organizational culture has a significant effect on the successful TQM implementation. For TQM programs to be succeed, a collaborative and corporate organizational culture supported by long-term management and employee commitment and involvement, organizational learning, innovation and entrepreneurship, team working and collaboration, open communication, risk taking, continuous improvement, customers focus (internal and external), partnership with suppliers, and monitoring and evaluation of quality should be developed. For TQM to be successful, an effective quality organization must be established to be channels for communication, the bureaucratic system must be transformed, a strategic plan must be established to be guidelines for execution, strategies and processes must be aligned and integrated within a quality culture, and the information system must be integrated.[134]

8.4 Measurement of Quality: Process versus Outcome

There is a debate in the literature about the relative merits of process and outcome measures. Some argue that process data often provide a more sensitive measure of quality than outcome data, since a poor outcome does not necessarily result from a failure in the provision of care. In addition, physicians usually define quality of care in terms of process. Outcomes are more generally perceived as poor measures of quality of care as they are only partially attributable to health services and may be more strongly influenced by other factors such as nutrition, environment, lifestyle or socioeconomic circumstances. Thus, outcomes of patients receiving the same treatment reflect to some extent patient characteristics rather than factors under the control of health care providers. Also, the interval between an intervention and its ultimate outcome may be lengthy and it may be difficult to attribute many outcomes of interest to the provision of particular services. Outcomes do not capture all elements of performance but only permit an inference about the quality of the processes and structures of care. Some contend that poor outcomes do not always imply poor quality of care. Furthermore, outcomes can be difficult and costly to measure and their measurement is subject to statistical uncertainty. At the same time, outcome measures are attractive as they are important in their own right, whereas a process measure by itself is usually of little intrinsic interest to those receiving the intervention. Also, it can be argued that outcome measures capture the sum of "all aspects of the processes of care and not simply those that are measurable or measured".[14]

8.5 Patient Focused

Robert Francis, QC, in his report on the Mid Staffordshire Foundation Trust Public Inquiry, stated that, while financial control, corporate governance, commissioning and regulatory systems are necessary, patients, not numbers, are what count in the healthcare system. Any system should be capable of caring and delivering an acceptable level of care to each patient treated, but his Inquiry showed that this cannot be assumed to be happening. He stated that the extent of the failure of the system shown in the report suggests that a fundamental culture change is needed. Patients must be put where they are entitled to be – the first and foremost consideration of the system and everyone who works in it.[12]

8.6 Barriers to Quality Management

8.6.1 Gaps in Transfer of Best Practices

Obstacles to the transfer of best practices to the healthcare sector were reviewed and two major gaps identified.[29]

- First, only a few project teams addressed core clinical processes such as physician decision-making, diagnostic strategies, and medical treatments. Most teams worked on business and service support processes such as appointment waiting times, Medicare billing, patient discharge processes, and the hiring and training of nurses. None of the teams measured success in terms of improved health status of the patient.
- Second, the projects did not try to change the organizational cultures. Clearly, both these gaps have to be addressed in any effort to improve performance along multiple dimensions in healthcare.[29]

8.6.2 Obstacles to Systems Thinking

The complexity of healthcare systems is an obstacle to systems thinking. There are powerful subcultures in healthcare organizations based on occupation and specialization, eg physicians, nurses, and pharmacists. These groups have their own definition of errors and quality in healthcare. Their interests and functional orientations may not facilitate a systems approach to the promotion of safety and performance improvements. Moreover, performance measurement and improvement programs within healthcare organizations do not directly address the problem of medical errors. Efforts by external organizations to monitor errors also face limitations.[29]

8.6.3 Obstacles to Successful TQM Implementation

Many organizations and companies have difficulties in implementing TQM. Failure of the TQM is attributed to lack of consistent senior management commitment and support, leadership style of managers – too top down or too laissez faire, superficial knowledge of the implementers of TQM, lack of a formalized strategic plan for change, vague improvement goals, unclear strategies and conflicting priorities, lack of developing and sustaining a quality oriented culture, lack of employees' motivation, participation and team working, employee apathy and resistance to change, lack of linkages between remuneration and firm's performance. There is also a lack of recognition for success, lack of training, education and technical knowledge and experience about TQM, poor coordination, close vertical communication (top down and bottoms up), lack of work discipline. The lack of resources and support, financial crisis, an organizational approach, a long-term focus and failure in understanding the voice of the customer will then affect corporate culture and cause problems in TQM successful implementation.[134]

8.6.4 Institution Level Decisions Affecting Work Conditions

There was a sense of frustration among both doctors and nurses that they could not provide the quality of care they felt they were capable of and motivated to provide due to institution-level decisions that affected their work conditions. A key theme in the interviews with both doctors and nurses was the impact of inadequate staffing and increasing administrative tasks on practitioners' ability to care for patients, and in particular their availability and motivation to ensure the more interpersonal aspects of care.[2]

8.6.5 Lack of Stakeholder Buy-In

Stakeholder buy-in is essential in any successful project, including Lean and Six Sigma efforts. A leading cause of project failure, however, is inattention to those stakeholders with the greatest influence over implementation and sustainability. Recurring stakeholder analysis will help the team determine the right approach to effective stakeholder communication, risk mitigation and engagement throughout the project. At each new phase, the stakeholder analysis needs to be revisited.[135]

8.6.6 Change Management for Sustained Improvement

Change management should be explicitly considered as an Six Sigma/Lean Six Sigma (SS/LSS) integral component since the results inevitably lead to significant process and/or behavioral changes. The new approaches and processes must be internalized by healthcare professionals to ensure ongoing use. In SS/LSS studies, statistical analysis is sometimes used to identify process variation sources. Process and other changes typically are developed in response to the major variation-drivers, but are sometimes implemented without statistical evidence that the change is valid. While 67 percent reported improvement in the key process metric at the SS/LSS study conclusion, only 9 percent reported sustained improvement. Additionally, only 28 percent reported cost savings and only 8 percent provided revenue enhancement. The limited reported impact on sustained metric improvement, cost savings and revenue enhancement does not favorably portray Six Sigma's overall effectiveness and the value it offers to healthcare.[136]

8.7 Evidence of What Works

Some studies and literature reviews addressing effectiveness of quality initiatives are reported below. Evidence of effectiveness of quality and safety models was not the objective of this literature review; therefore, those included are incidental and the information included for interest.

- A study to explore the mediating effects of three Performance Improvement (PI) programs for the impact on medical errors was reported. The findings were that:
  - For enhancing patient safety outcomes, CQI and Lean were significant in mediating hospital error sources; however, Six Sigma was not significant after accounting for the other two PI types.
  - For improving organizational effectiveness, CQI and Six Sigma were significant, whereas Lean was not significant over and above the other two PI types.
  - Finally, only Six Sigma was significant for superior sustainable competitive advantage.[40]
- A case-study methodology was used to assess the application of aviation industry-based innovations in the hospital, with a focus on the context and the detailed mechanism for each innovation. Aviation industry–based innovations diffused into patient care processes were as follows: patient planning and booking system, taxi service/valet parking, risk analysis (as applied to wrong-site surgery), time-out procedure (also for wrong-site surgery), Crew Resource Management training, and black box. Observations indicated that the innovations had a positive effect on quality and safety in the hospital: waiting times were reduced, work processes became more standardized, the number of wrong-site surgeries decreased, and awareness of patient safety was heightened.[137]
- A Systematic review was done including nine studies describing continuous quality improvement (CQI), five Six Sigma, five total quality management (TQM), five plan-do-study-act (PDSA) or plan-do-check-act (PDCA) cycles, five statistical process control (SPC) or statistical quality control (SQC), four Lean and one Lean Six Sigma. 20 of the studies were undertaken in the US. The most common aims were to reduce complications or improve outcomes (11), to reduce infection (7), and to reduce theatre delays (7). There was one randomized controlled trial. The conclusion was that QI methodologies from industry can have significant effects on improving surgical care, from reducing infection rates to increasing operating room efficiency. It was stated that the evidence was generally of suboptimal quality, and rigorous randomized multicentre studies are needed to bring evidence-based management into the same league as evidence-based medicine.[138]

9.0 Limitations

A vast amount of literature is available on the subjects of quality and safety management. This literature review sought to identify 'models' in existence in healthcare, industry and management over the past twenty years from both published and grey literature. The literature findings represent a variety of types of concepts, from full blown 'models' to approaches, tools, philosophies. Many are inter-related and overlap. An effort has been made to organize these for ease of the reader. Because of the plethora of quality and safety 'models', only a brief description of each has been included in the report. Further, in depth, research will be needed to understand and evaluate those of interest.

10.0 Conclusions

Through review of provincial, national and international published and grey literature from the past twenty years, this report has presented a summary of a wide variety of safety and quality management models, approaches, concepts and tools from healthcare as well as from industry and management. Brief information is provided for each as an introduction to the concept only. More in depth information will be required should there be a desire to further pursue a specific model or concept.

Conflicts of Interest

Janet Adams is Principal, Altus Planning Inc. Tamara Durec is President, Durec Information Systems Inc. The authors declare that they have no conflicts of interest.

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Note: Grey literature highlighted in grey

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Appendices

Appendix 1: Electronic Search Strategies

Topic: Literature review to provide background information for the development of a provincial model of quality management in healthcare settings.

Databases: MEDLINE, EMBASE, Health Business Elite, Compendex, Emerald Insight, ABI Inform Global

Limits: 1993-current (Dec 2013) (last 20 years)

Language: English

Study design/publication type: no limits

Search Summary

Database	Results	Duplicates between databases removed (de-duped)
MEDLINE	2253	2067
EMBASE	1138	1133
Health Business Elite	906	906
Compendex	1764	1764
Emerald Insight	198	198
ABI Inform Global	559	559
TOTALS	6818	6627

Search Strategies

Ovid MEDLINE 1946 to December 30, 2013, Ovid MEDLINE In-Process & Other Non-Indexed Citations, and Ovid MEDLINE Daily

Version: OvidSP_UI03.10.00.104, SourceID 59019

Search date: 31.12.2013

Limits: 1993-current, English

Results: 2253 De-duped: 2067

1. Models, Organizational/ and management.tw.
2. (organi#ational and (quality adj3 (management or model$ or framework?))).mp.
3. (management adj2 (model$ or framework?)).tw.
4. quality management.tw.
5. (quality and ((continuous$ or total) adj3 (management or model$ or framework?))).tw.
6. ((continuous$ or total) and (quality adj3 (management or model$ or framework?))).tw.

7. (TQM or CQI).tw.
8. Total Quality Management/
9. (UMIST Quality Improvement Framework or UMIST Model).tw.
10. ("Model for Improvement" and management).tw.
11. (plan do check or PDCA or plan do study or PDSA).tw.
12. (LEAN adj (production or manufactur$ or approach or management or method? or methodology or thinking or enterpri#e or practice or philosophy or principles)).tw.
13. Six Sigma.tw.
14. Kaizen.tw.
15. Toyota Production System.tw.
16. Balanced Scorecard.tw.
17. ((object oriented or integrated) adj quality management).tw.
18. (European Foundation for Quality Management Excellence Model or EFQM).tw.
19. (Management By Walking About or MBWA).tw.
20. Malcolm Baldridge National Quality Award.tw.
21. ((Institute of Healthcare Improvement or IHI) and (management or model$ or framework?)).tw.
22. DMAIC.tw.
23. McKinsey 7-S Framework.tw.
24. "ISO 9000".tw.
25. (juran or deming or feigenbum or ishikawa or taguchi or shingo or crosby or peters or reason or shewhart or shewart or berwick).tw.
26. Organizational Culture/
27. Organizational Innovation/
28. ((organi#ation$ and (culture or innovat$)) adj5 (management or model$ or framework?)).mp.
29. or/1-28 [models]
30. safety/ or patient safety/ or safety management/
31. safety management.tw.
32. (patient adj2 (safety or harm? or threat?)).tw.
33. exp Medical Errors/ and management.tw.
34. ((clinical or medical or medication or drug or diagnos$ or surgery or surgical) adj2 (error? or event or harm? or threat?)).tw.
35. ((adverse adj2 event) and (management or report$)).tw.
36. ((patient adj2 (safety or harm? or threat?)) and management).tw.
37. Risk Assessment/
38. Risk Factors/
39. Risk Management/
40. (risk? adj2 (assessment? or analys$ or factor? or management)).tw.
41. (hazard? adj2 (identification or surveil$ or assessment? or factor? or management or control? or analys$)).tw.
42. or/30-41 [safety]
43. "Quality of Health Care"/
44. "Outcome and Process Assessment (Health Care)"/
45. Quality Assurance, Health Care/
46. Quality Improvement/
47. (quality and (assurance or management)).tw.
48. (quality adj2 (care or healthcare)).tw.
49. or/43-48 [quality]
50. and/29,42,49 [models & safety & quality]
51. limit 50 to (english language and yr="1993 -Current")
52. (rat or rats or cow or cows or chicken? or horse or horses or mice or mouse or rabbit? or bovine or animal?).ti.
53. 51 not 52
54. remove duplicates from 53

EMBASE 1980 to 2013 December 31 Week 51

Version: OvidSP_UI03.10.00.104, SourceID 59019

Searched: 31.12.2013

Limits: English, date range 1993-current

Results: 1138 de-duped: 1133

1. model/ and management.tw.
2. exp management/ and (model$ or framework?).tw.
3. exp "organization and management"/ and (model$ or framework?).tw.
4. (organi#ational and (quality adj3 (management or model$ or framework?))).mp.
5. (management adj2 (model$ or framework?)).tw.
6. quality management.tw.
7. (quality and ((continuous$ or total) adj3 (management or model$ or framework?))).tw.
8. ((continuous$ or total) and (quality adj3 (management or model$ or framework?))).tw.
9. (TQM or CQI).tw.
10. total quality management/
11. (UMIST Quality Improvement Framework or UMIST Model).tw.
12. ("Model for Improvement" and management).tw.
13. (plan do check or PDCA or plan do study or PDSA).tw.
14. (LEAN adj (production or manufactur$ or approach or management or method? or methodology or thinking or enterpri#e or practice or philosophy or principles)).tw.
15. Six Sigma.tw.
16. Kaizen.tw.
17. Toyota Production System.tw.
18. Balanced Scorecard.tw.
19. ((object oriented or integrated) adj quality management).tw.
20. (European Foundation for Quality Management Excellence Model or EFQM).tw.
21. (Management By Walking About or MBWA).tw.
22. Malcolm Baldridge National Quality Award.tw.
23. ((Institute of Healthcare Improvement or IHI) and (management or model$ or framework?)).tw.
24. DMAIC.tw.
25. McKinsey 7-S Framework.tw.
26. "ISO 9000".tw.
27. (juran or deming or feigenbum or ishikawa or taguchi or shingo or crosby or peters or reason or shewhart or shewart or berwick).tw.
28. ((organi#ation$ and (culture or innovat$)) adj5 (management or model$ or framework?)).mp.
29. or/1-28 [models]
30. exp environment/ and (safety or management).tw.
31. safety management.tw.
32. (patient adj2 (safety or harm? or threat?)).tw.
33. exp medical error/ and management.tw.
34. ((clinical or medical or medication or drug or diagnos$ or surgery or surgical) adj2 (error? or event or harm? or threat?)).tw.
35. ((adverse adj2 event) and (management or report$)).tw.
36. ((patient adj2 (safety or harm? or threat?)) and management).tw.
37. exp "danger, risk, safety and related phenomena"/
38. (risk? adj2 (assessment? or analys$ or factor? or management)).tw.
39. (hazard? adj2 (identification or surveil$ or assessment? or factor? or management or control? or analys$)).tw.
40. or/30-39 [safety]
41. health care quality/

42. outcome assessment/
43. (quality and (assurance or management)).tw.
44. (quality adj2 (care or healthcare)).tw.
45. or/41-44 [quality]
46. and/29,40,45 [models & safety & quality]
47. limit 46 to (english language and yr="1993 -Current")
48. (rat or rats or cow or cows or chicken? or horse or horses or mice or mouse or rabbit? or bovine or animal?).ti.
49. 47 not 48
50. limit 49 to exclude medline journals
51. remove duplicates from 50

Health Business Elite

Interface – EBSCOhost Research Databases

Search Mode – Find all my search terms

Search date: 31.12.2013

Limits: 1993-current, English, peer reviewed

Results: 906 De-duped: 906

#	Query
S41	S22 AND S33 AND S37 [models & safety & quality]
S40	S22 AND S33 AND S37
S39	S22 AND S37
S38	S22 AND S33
S37	S34 OR S35 OR S36 [quality]
S36	quality W2 care or quality W2 healthcare
S35	quality AND (assurance or management)
S34	((DE "QUALITY" OR DE "QUALITY assurance") AND (DE "TAGUCHI methods (Quality control)" OR DE "MEDICAL care -- Quality control")) OR (DE "OUTCOME assessment (Medical care)")
S33	S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 [safety]
S32	DE "AERONAUTICS -- Human factors" OR DE "AIRPLANES -- Piloting -- Human factors" OR DE "AUTOMATION -- Human factors" OR DE "NUCLEAR power plants -- Human factors"
S31	hazard* W2 assessment* or hazard* W2 analys* or hazard* W2 factor* or hazard* W2 management
S30	DE "HAZARDS" OR DE "FLIGHT hazards"
S29	risk W2 assessment* or risk W2 analys* or risk W2 factor* or risk W2 management
S28	DE "RISK" OR DE "RISK assessment" OR DE "RISK management in business"

S27	adverse W2 event* AND (management or report*)
S26	(clinical or medical or medication or drug or diagnos* or surgery) AND (error* or event or harm* or threat*)
S25	patient W2 safety or patient W2 harm* or patient W2 threat*
S24	safety management
S23	(DE "SAFETY" OR DE "INDUSTRIAL safety" OR DE "MARITIME safety") OR (DE "AERONAUTICS -- Safety measures" OR DE "MERCHANT marine -- Safety measures" OR DE "TRAFFIC safety" OR DE "SYSTEM safety" OR DE "SAFETY factor in engineering" OR DE "NUCLEAR weapons safety" OR DE "OIL fields -- Safety measures" OR DE "TRANSPORTATION -- Safety measures" OR DE "RAILROADS -- Safety measures" OR DE "HAZARD Analysis & Critical Control Point (Food safety system)" OR DE "SPACE flight -- Safety measures" OR DE "PIPELINES -- Safety measures" OR DE "OFFSHORE oil well drilling -- Safety measures" OR DE "PROCESS safety management" OR DE "NUCLEAR energy -- Safety measures" OR DE "NUCLEAR engineering -- Safety measures" OR DE "HAZARDOUS substances -- Transportation -- Safety measures" OR DE "POWER plants -- Safety measures" OR DE "NUCLEAR industry -- Safety measures" OR DE "HOSPITALS -- Safety measures" OR DE "PATIENTS -- Safety measures" OR DE "CHEMICALS -- Safety measures")
S22	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 [models]
S21	organi#ation* AND (innovat* W5 management or innovat* W5 model* or innovat* W5 framework*)
S20	organi#ation* AND (culture W5 management or culture W5 model* or culture W5 framework*)
S19	juran or deming or feigenbum or ishikawa or taguchi or shingo or crosby or peters or reason or shewhart or shewart or berwick
S18	(Institute of Healthcare Improvement or IHI) AND (management or model* or framework*)
S17	ISO 9000
S16	Object Oriented Quality Management or Integrated Quality Management or European Foundation for Quality Management Excellence Model or EFQM or Management By Walking About or MBWA or Malcolm Baldridge National Quality Award
S15	Six Sigma or Kaizen or Toyota Production System or Balanced Scorecard or DMAIC or McKinsey 7-S Framework
S14	DE "INNOVATION management" OR DE "LEAN manufacturing" OR DE "AGILE manufacturing systems" OR DE "JUST-in-time systems" OR DE "PROCESS optimization" OR DE "SIX Sigma (Quality control standard)" OR DE "VALUE stream mapping"
S13	LEAN W1 production or LEAN W1 manufactur* or LEAN W1 approach or LEAN W1 management or LEAN W1 method* or LEAN W1 thinking or LEAN W1 enterpri#e or LEAN W1 practice or LEAN W1 philosophy or LEAN W1 principles
S12	plan do check or PDCA or plan do study or PDSA
S11	"Model for Improvement" and management
S10	UMIST Quality Improvement Framework or UMIST Model

S9	(DE "AIRLINE industry -- Management" OR DE "AIRPORTS -- Management" OR DE "ASSOCIATIONS, institutions, etc. -- Management" OR DE "BALANCED scorecard (Management)" OR DE "BANK management" OR DE "BUSINESS" OR DE "BUSINESS logistics management" OR DE "COMMAND & control systems" OR DE "COMPARATIVE management" OR DE "COMPUTER programming -- Management" OR DE "CONTINGENCY theory (Management)" OR DE "CORPORATE flight departments -- Management" OR DE "EMERGENCY management" OR DE "ENVIRONMENTAL management" OR DE "EVIDENCE-based management" OR DE "EXECUTIVES" OR DE "FACILITY management" OR DE "FARM management" OR DE "FINANCE departments" OR DE "FOOD industry -- Management" OR DE "FOOD service management" OR DE "HOSPITALITY industry -- Management" OR DE "HOSPITALS -- Administration" OR DE "HOTEL management" OR DE "INDUSTRIAL management" OR DE "INTERACTIVE management" OR DE "LINE & staff organization" OR DE "MANAGEMENT science" OR DE "MANAGEMENT styles" OR DE "MANAGERIAL economics" OR DE "MISMANAGEMENT" OR DE "OFFICE management" OR DE "ORGANIZATIONAL behavior" OR DE "ORGANIZATIONAL change" OR DE "ORGANIZATIONAL effectiveness" OR DE "PLANNING" OR DE "POLICE administration" OR DE "PRISON administration" OR DE "PROBLEM solving" OR DE "PROJECT management" OR DE "PUBLIC institutions -- Management" OR DE "REENGINEERING (Management)" OR DE "RESOURCE allocation" OR DE "RESOURCE management" OR DE "RESTAURANT management" OR DE "RETAIL stores -- Management" OR DE "REVENUE management" OR DE "RISK management in business" OR DE "THEORY of constraints (Management)" OR DE "TOTAL quality management" OR DE "VALUE-based management" OR DE "WATER demand management" OR DE "WATER quality management" OR DE "WORK environment -- Management" OR DE "WORK measurement" OR DE "WORKFLOW") AND (model or framework)
S8	TQM or CQI
S7	(continuous* or total) AND (quality W3 management or quality W3 model* or quality W3 framework*)
S6	quality AND (total W3 management or total W3 model* or total W3 framework*)
S5	quality AND (continuous* W3 management or continuous* W3 model* or continuous* W3 framework*)
S4	TI quality management OR AB quality management
S3	management W2 model* or management W2 framework*
S2	organi#ational AND (quality W3 management or quality W3 model* or quality W3 framework*)
S1	DE "BUSINESS models" OR DE "EFQM Excellence Model"

ABI Inform Global (Proquest, 1970-Current)

Search date: 30.12.2013

Limits: 1993-current, English, Peer reviewed

Exclude:

Classification: Experimental/theoretical; Experiment/theoretical treatment; Statistical data; Investment analysis & personal finance; Acquisitions & mergers; Experimental/theoretical treatment; Social policy; Regulation; Economic theory; Social responsibility; Capital & debt management; Employee benefits & compensation; Market research; Marketing; Research & development; Legislation; Life & health insurance; Accounting policies & procedures; Social trends & culture; Economic conditions & forecasts; Economic policy & planning; Credit management; International trade & foreign investment; Litigation

Results: 559 De-duped: 559

(((all(business OR organization* OR organisation* OR management) AND all((model* OR framework*))) AND (all(quality) AND all(assurance OR assess* OR improv* OR manag* OR indicator?))) OR (su(models) AND su(management)) OR (organi?ational AND (quality NEAR/3 (manag* OR model* OR framework?))) OR all((quality AND ((continuous* OR total) NEAR/3 (manag* OR improv* OR model* OR framework?))))) OR all(((continuous* OR total) AND (quality NEAR/3 (manag* OR improv* OR model* OR framework?))))) OR all("six sigma" OR "toyota production system" OR "balanced scorecard" OR "total quality improvement" OR TQM OR CQI OR "plan do check" OR PDCA OR "plan do study" OR PDSA OR "object oriented quality management" OR "European Foundation for Quality Management Excellence Model" OR EFQM OR "Management By Walking About" OR MBWA OR "Malcolm Baldridge National Quality Award" OR DMAIC OR "McKinsey 7-S Framework" OR "ISO 9000") OR all((LEAN PRE/1 (production OR manufactur* OR approach OR management OR method? OR methodology OR thinking OR enterpri?e OR practice OR philosophy OR principles))) OR (all("Institute of Healthcare Improvement" OR IHI) AND all(manag* OR improv* OR model* OR framework?)) OR all(juran OR deming OR feigenbum OR ishikawa OR taguchi OR shingo OR crosby OR peters OR reason OR shewhart OR shewart OR berwick) OR (all(organi?ation*) AND all(((culture OR innovat*)) NEAR/5 all ((manag* OR model* OR framework?))))) AND (all(safety) OR (all(error? OR risk? OR event? OR harm? OR threat? OR hazard?) AND all(assessment? OR analys* OR factor? OR manag* OR improv* OR identification OR surveil* OR control?))) AND (all(quality) AND all(assurance OR assess* OR improv* OR manag* OR indicator?))Limits applied

Compendex (Engineering Index, 1984-current)

Search date: 31.12.2013

Limits: 1993-current, English

Results: 1764 De-duped: 1764

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OR$berwick) WN KY) AND (1993-2014 WN YR)) OR ((((({Innovation} WN CV)))) AND (1993-2014 WN YR)) OR (((organi?ation* AND (culture NEAR/5 management OR model* OR framework*))) AND (1993-2014 WN YR)) OR (((organi?ation* AND (innovat* NEAR/5 management OR model* OR framework*))) AND (1993-2014 WN YR)))) AND ({english} WN LA))) AND (1993-2014 WN YR)) AND (((((((((({Accident prevention} WN CV) OR ({Safety factor} WN CV) OR ({Hazards} WN CV) OR ({Safety engineering} WN CV) OR ({Disaster prevention} WN CV) OR ({Risk assessment} WN CV) OR ({Risk management} WN CV) OR ({Risk analysis} WN CV))))) AND ({english} WN LA))) AND (1993-2014 WN YR)) OR ((((risk OR hazard) WN KY) AND ((identification OR surveil* OR assessment OR factor? OR management OR control OR analys*) WN KY)) AND (English WN LA) AND (1993-2014 WN YR))) AND (1993-2014 WN YR)) AND ((((((({Quality management} WN CV) OR ({Quality assurance} WN CV) OR ({Quality control} WN CV) OR ({Taguchi methods} WN CV)))) AND (English WN LA) AND (1993-2014 WN YR)) OR ((((quality) WN KY) AND ((assurance OR management) WN KY)) AND (English WN LA) AND (1993-2014 WN YR))))) AND (({ja} OR {rr}) WN DT)) NOT (({922.1} OR {921} OR {421} OR {922.2} OR {911} OR {911.2} OR {408.1} OR {922} OR {902.3} OR {723.2} OR {921.6} OR {422.2}) WN CL))

Emerald Insight

http://www.emeraldinsight.com

Search date: 29.12.2013

Limits: 1993-current, English

Results: 198

Search queries

Content = Journals, *((business or organization or organisation or management) AND (model* or framework*)* in All fields) and *(safety or risk or hazard* in All fields) and *(quality* in All fields)

Content = Journals, *(quality management* in All fields) and *(model* or framework** in All fields) and *(business or healthcare* in All fields), article type = Literature review, between 1993 & 2014

Content = Journals, *(quality management* in All fields) and *(model* or framework** in All fields), article type = Literature review, between 1993 & 2014, inc. EarlyCite articles, inc. Backfiles content

Grey Literature Search

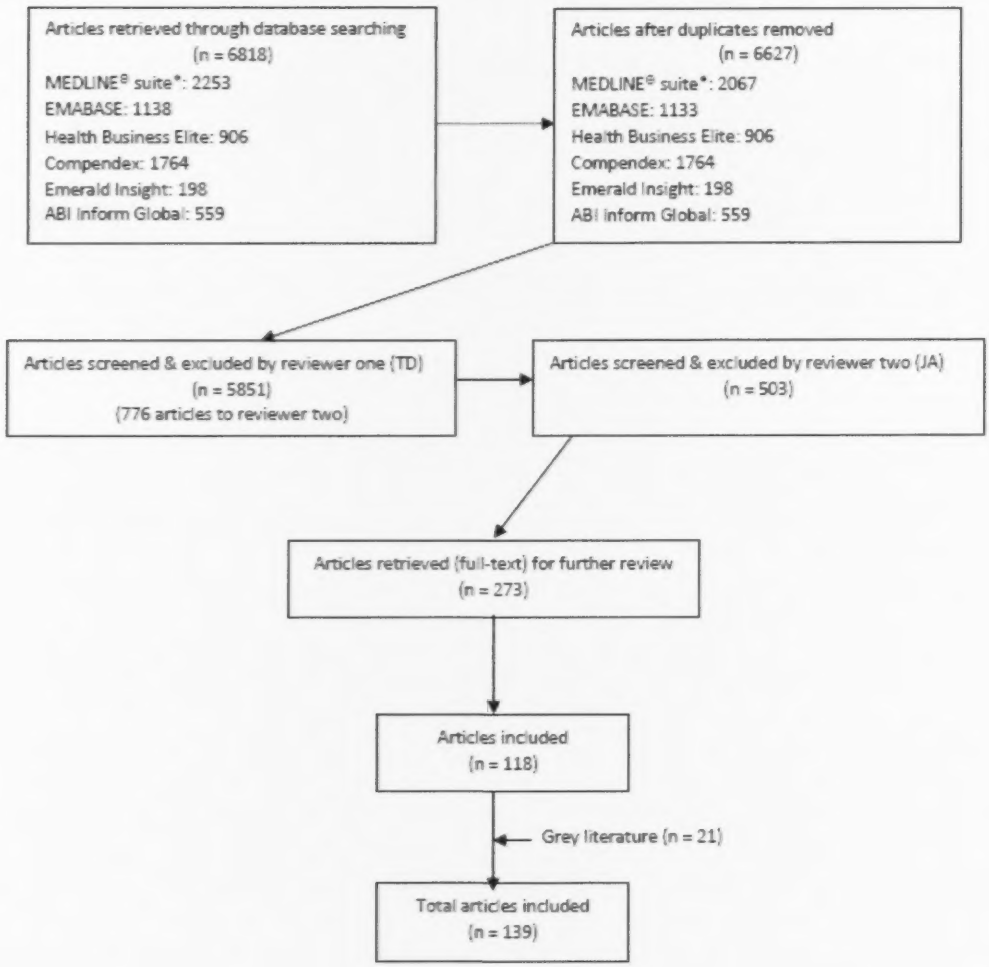
Table: Summary Grey Literature Websites Searched

Website	URL
AHRQ PSNet: Patient Safety Network	http://psnet.ahrq.gov
American Society for Quality (ASQ)	http://asq.org
European Union Network for Patient Safety and Quality of Care (PaSQ)	http://www.pasq.eu
Institute for Healthcare Improvement (IHI)	http://www.ihi.org
Institute of Medicine (IOM)	http://www.iom.edu
International Air Transport Association (IATA)	https://www.iata.org

International Civil Aviation Organization (ICAO)	http://www.icao.int
Kings Fund	http://www.kingsfund.org.uk
NHS (England)	http://www.england.nhs.uk
NHS Improving Quality (NHS IQ)	http://www.nhsiq.nhs.uk
SKYbrary	http://www.skybrary.aero/index.php/Main_Page
Transport Canada	http://www.tc.gc.ca

Appendix 2: Article Flow Chart

Article Flow Chart – Quality Management Models Literature Review



*MEDLINE® suite: MEDLINE®, MEDLINE® In-Process & Other Non-Indexed Citations, and MEDLINE® Daily

Appendix V: Current interRAI quality indicators

Long-term care

ADL

- Unexpected loss of function in basic daily activities
- Improved mid-loss activities of daily living (ADL) functioning (transfer and locomotion) or remained completely independent in mid-loss ADLs
- Improved early-loss ADL functioning (dressing and personal hygiene) or remained completely independent in early-loss ADLs
- Improved in some basic daily activities
- Declined mid-loss ADL functioning (transfer and locomotion) or remained completely dependent in mid-loss ADLs
- Declined early-loss ADL functioning (dressing and personal hygiene) or remained completely dependent in early-loss ADLs
- ADL self-performance declined

Behaviour

- Behaviour symptoms declined
- Behaviour symptoms improved

Continence

- Residents with indwelling catheters
- Residents whose bowel continence worsened
- Residents whose bladder continence worsened
- Residents with a urinary tract infection
- Residents whose bowel continence improved
- Residents whose bladder continence improved

Cognitive Function

- Cognitive ability worsened
- Cognitive ability improved

Communication

- Ability to communicate worsened
- Ability to communicate improved

Delirium

- Residents with symptoms of delirium

Falls

- Fell in last 30 days

Infection

- Residents with infections
- New respiratory infection or not improved

Mobility

- Locomotion ability worsened
- Locomotion ability improved

Mood

- Worsened symptoms of depression

Nutrition/Weight

- Residents with feeding tube
- Unexplained weight loss

Pain

- Residents with pain
- Worsened pain

Pressure Ulcer

- Pressure ulcers at stage 2-4
- Worsened pressure ulcers at stage 2-4
- New pressure ulcer at stage 2-4

Restraints

- Residents in physical restraints

Medication

- Antipsychotics without indicators of psychosis

Home care

Functional Indicators

- Improvement in instrumental ADL
- Decline in instrumental ADL
- Improvement in ADL
- Decline in ADL
- Improvement in cognitive performance
- Decline in cognitive performance
- Improvement in communication
- Decline in communication

Clinical Indicators

- Improvement in bladder continence
- Decline in bladder continence
- Occurrence of falls at follow-up
- Unexpected weight loss at follow-up
- Injuries at follow-up
- Improvement in mood symptoms
- Decline in mood symptoms
- Daily, severe pain at follow-up
- Pain not adequately controlled

Social Indicators

- Caregiver distress at follow-up
- Social isolation and distress
- Reduced community involvement

Health Services Indicators

- No influenza vaccination
- Hospital, emergency department, emergent care use at follow-up

Appendix VI: Development of interRAI assessments

Development of the interRAI assessment systems began with the release of the original Resident Assessment Instrument (RAI) version 1.0 for nursing home settings in 1990 as a response to an Institute of Medicine report on the quality of long term care in the United States.[134] The interRAI network was established in 1992 to begin a program of international research aimed at conducting cross-national comparative research in nursing homes.[134] The RAI instrument was updated to its second version in 1994 in research led by the US Health Care Financing Administration in partnership with US members of the interRAI network[134] A series of evaluation studies demonstrated that the introduction of the RAI into US nursing homes was associated with improved quality of care in multiple domain areas.[134]

By the mid-1990's the focus of interRAI research expanded to included development of new assessment instruments for home care,[135] inpatient psychiatry,[124] and acute care.[136] These were initially conceived of as "stand-alone", but complementary, systems; however, by 2000 it was recognized that these instruments could be seen to comprise an integrated health information system linking multiple sectors of care.[137] A multi-year restructuring initiative was launched in order to update the entire family of existing interRAI instruments and to develop new instruments for sectors not already covered by existing assessments.[126,138] The aim of this new effort was to fully harmonize assessment methodologies, item definitions, and care planning approaches in order to comprise an assessment approach that would cover the full continuum of care. The table below provides a list of all new interRAI assessment systems that comprise the new, integrated suite of instruments.

The effort to update all interRAI instruments included a multinational effort to update the RAI 2.0. Given the broad international use of this instrument, there was great interest in many countries to update the instrument and to tailor it to the needs of all countries employing the instrument. Where previous developmental work had been restricted to the US only, the research effort to update the RAI 2.0 was a broad international effort including strong participation from Canadian researchers, long term care organizations and CIHI. A 12-country study of the reliability of the new interRAI instruments[138] showed that the new instruments had improved performance in reliability compared with previous instruments and that reliability levels were comparable across various care settings including home care, nursing homes, post-acute care, palliative care and mental health.

The new interRAI Long Term Care Facility (LTCF) assessment system that arose from this restructuring effort bears many advantages over the RAI 2.0, including improved reliability, reduced length (30% shorter than RAI 2.0), easier administration, refined items and scales, and expansion of items related to the resident's perspective[139,140] However, the key advantage of the interRAI LTCF is that it is fully harmonized with all new interRAI instruments, whereas the RAI 2.0 in current use employs older item response sets that require some adaption to compare with other interRAI assessments.

The interRAI LTCF has been the focus of a large scale multi-national study on nursing home care in the European Union known as the SHELTER Project.[140] The study used the LTCF to examine clinical issues like depression,[141,142] delirium,[143] inappropriate drug use,[144] polypharmacy[145] and diabetes care[146] in European nursing homes. However, a study of critical importance was done by Boorsma et al., who showed that the interRAI LTCF was associated with improved quality of care and quality of life in Dutch nursing homes as part of a randomized clinical trial.[147]

In the foreseeable future it will be important for Canadian jurisdictions to move to adopt the newer interRAI LTCF instrument because it is more cost effective, more psychometrically sound, and more

closely integrated with other interRAI instruments in use in Canada than the RAI 2.0. CIHI has begun an initiative to update its reporting systems to receive data based on the new interRAI instruments. This has been spurned, at least in part by the current or planned adoption of new suite instruments in Ontario (Contact Assessment, Home Care, Palliative Care, Community Health Assessment), Manitoba (Long Term Care Facility), and Newfoundland and Labrador (Community Mental Health). Considerable work has been done by interRAI and CIHI to ensure that important applications like care planning protocols, outcome measures, quality indicators and case mix classification systems can be fully derived from the new instruments.

The new suite of interRAI assessment instruments

Care setting	interRAI Assessment	Supplements or Screeners
Nursing homes Complex continuing care hospitals	interRAI Long Term Care Facility (LTCF)	
Home care	interRAI Home Care (HC)	Contact Assessment
Community support services Assisted living Primary care	interRAI Community Health Assessment (CHA)	Functional Supplement Mental Health Supplement Deafblind Supplement Assisted Living Supplement
Acute care	interRAI Acute Care (AC)	ED Screener ED Contact Assessment Post-acute supplement
Rehabilitation	interRAI Post Acute Care (PAC)	
Inpatient psychiatry	interRAI Mental Health (MH)	Forensic Supplement Addictions Supplement (In development)
Community mental health	interRAI Community Mental Health (CMH)	Forensic Supplement Addictions Supplement (In development)
Mental health crisis (e.g., emergency room, mobile crisis teams)	interRAI Emergency Screener for Psychiatry (ESP)	
Pediatric Residential Mental Health	interRAI Child Youth Mental Health (ChYMH)	Adolescent Supplement Addictions Supplement (In development)
Developmental Services	interRAI Intellectual Disability (ID)	
Pediatric Developmental Services	interRAI Child Youth Mental Health – Developmental Disability (ChYMH – DD)	
"Patient Experience" Surveys	interRAI Self-reported Quality of Life Surveys	Nursing Home Home Care Independent Living Senior Housing Mental Health

Appendix VII: Interim report

HQCA

Promoting and improving patient safety and health service quality across Alberta

February 28, 2014

Honourable Fred Horne
Minister
Office of the Minister
Alberta Health
208 Legislature Building
10800 - 97 Avenue
Edmonton, AB T5K 2B6

Dear Minister Horne:

As requested in the Terms of Reference for the HQCA's Review of Quality Assurance in Continuing Care Health Services in Alberta, attached is an interim report of the Health Quality Council of Alberta's progress.

This report describes the HQCA's work to-date, as well as a brief outline of our next steps. As mentioned in the report, at this early stage we cannot report on findings or speculate on recommendations as we are still gathering information and in the early stages of analysis.

The HQCA is proud to have the opportunity to conduct this work on behalf of Albertans, and we look forward to providing you with the final report.

Sincerely,

Patricia Pelton
Acting CEO, HQCA
Chair, HQCA Quality Assurance Committee

cc: A.L.A. (Tony) Fields, Chair, Health Quality Council of Alberta
Janet Davidson, Deputy Minister, Alberta Health

[illegible]

HQCA

Review of Quality Assurance in Continuing Care Health Services in Alberta

Interim Progress Report – February 28, 2014

Review of Quality Assurance in *Home Care Services*

On September 9, 2013, the Minister of Health directed the HQCA to review and report on quality assurance with respect to the provision of home care services. The HQCA struck a quality assurance committee (QAC) to conduct the review in accordance with section 9 of the *Alberta Evidence Act*, and developed a terms of reference which were then approved by the HQCA Board Chair. A project charter was developed by the QAC and approved by the HQCA Acting Chief Executive Officer.

Key activities by the QAC at this stage related to quality management/quality assurance for home care services included:

- engaging external experts
- initiating interviews
- requesting relevant documents
- initiating document review
- conducting an extensive literature review

Review of Quality Assurance in *Continuing Care Services*

On December 2, 2013, the Minister of Health expanded the review of quality assurance in home care to include the provision of continuing care services (home living, supportive living, and long-term care).

The Terms of Reference were subsequently revised to include quality assurance for all of continuing care, which were approved by the HQCA Board Chair. The project charter was also revised by the QAC and approved by the HQCA Acting Chief Executive Officer.

The QAC expanded the interview roster and document request to include all three streams of continuing care. A second literature review was completed with a broader focus on quality management in general and beyond just home care services.

More than 40 interviews with key stakeholders have been conducted to date, representing Alberta Health, Alberta Health Services (including the five AHS zones), continuing care contracted providers and associated organizations in the continuing care field.

The more than 400 documents received and reviewed include contracts, directional and operational policies, provincial government reports, strategic plans, quality indicator reports, provincial standards and auditing tools and processes, consultant reports, and governance and organizational structures that support quality and safety management in continuing care.

Building on the request by the Minister to look at quality assurance, the QAC will be addressing quality management practices for continuing care, which includes performance indicators or measures, quality improvement processes, resident/family experience feedback, complaints, adverse event monitoring, accreditation, and monitoring and compliance with standards.

At this stage it is not possible to report findings, and it is too early to speculate on recommendations. There is still a considerable amount of information to collect and consider before drawing any conclusions.

Next steps:

March and April will be critical months in the review process. The QAC is planning the following work for this stage:

- Continue to identify and review relevant documents.
- Continue interviews with a targeted completion of the end of March.
- Analyze information and start developing the report with findings and recommendations.
- Targeting completion for April 30, 2014.

Appendix VIII: Acronyms

ADL	Activities of daily living
AH	Alberta Health
AHS	Alberta Health Services
AIW	Alberta Health Services improvement way
BAS	Business Advisory Services
CAPs	Clinical assessment protocols
CC	Continuing care
CCHSS	Continuing Care Health Service Standards
CCQMF	Continuing care quality management framework
CEO	Chief executive officer
CIHI	Canadian Institute for Health Information
CPSM	Contracting, procurement and supply management
DIMR	Data Integration, Measurement & Reporting
ELT	Executive leadership team
FACT	Feedback and concerns tracking
FIRMS	Financial information reporting measurement system
FL	Facility living
FTE	Full time equivalent
HC	Home care
HCA	Health care aide
HL	Home living
HQCA	Health Quality Council of Alberta
HS&QM	Healthcare Safety & Quality Management
IHI	The Institute for Healthcare Improvement
IT	Information technology
LPN	Licensed practical nurse
LTC	Long-term care
MCOC	Major contracts oversight committee
MDS	Minimum data set
MLA	Member of the Legislative Assembly
MSA	Master services agreement
PA	Parliamentary assistant
PARIS	Primary access regional information system
PCBF	Patient care based funding
PCC	Primary community care
PDD	Persons with developmental disabilities
PPC	Protection for Persons in Care
QA	Quality assurance
QHI	Quality & healthcare improvement
QI	Quality improvement
QIPE	Quality improvement policy and evaluation
QM	Quality management

RAI	Resident Assessment Instrument
RFP	Request for proposal
RLS	Reporting and learning system
RN	Registered nurse
RUGs	Resource utilization groups
SCN	Strategic Clinical Network
SL	Supportive living
SQLI	Seniors Quality Leap Initiative

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